HIT Policy Committee
Draft Transcript
February 17, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Great, thank you. Good morning, everybody, and welcome to the ninth meeting of the HIT Policy Committee. Just a reminder, this is a federal advisory committee. There will be opportunity at the close of the meeting for the public to make comment either here in the room or on the phone or Web. Committee members, please remember to identify yourselves when speaking for attribution. Minutes of the meeting will be posted on the ONC Web site. With that let me ask members of the committee to introduce themselves around the table beginning with Jodi Daniel.

Jodi Daniel – ONC – Director Office of Policy & Research
Jodi Daniel, ONC.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Scott White, 1199.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Jim Borland, Social Security Administration.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Paul Egerman – eScription – CEO
Paul Egerman, software entrepreneur.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Adam Clark, Live Strong.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
Larry Wolf for Rick Chapman, Kindred Healthcare.

Neil Calman – Institute for Family Health – President & Cofounder
Neil Calman, Institute for Family Health.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, National Coordinator.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women & Families.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst, Intermountain Healthcare.

Gayle Harrell – Florida – Former State Legislator
Gayle Harrell, Former State Legislator, Florida.

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw, the Center for Democracy & Technology.

Tony Trenkle – CMS – Director of OESS
Tony Trenkle, Centers for Medicare and Medicaid Services.

Charles Kennedy – WellPoint – VP for Health IT
Charles Kennedy, WellPoint.

Judy Sparrow – Office of the National Coordinator – Executive Director
We have a few committee members on the telephone. David Lansky, are you there? Connie White-Delaney?

Connie Delaney – University of Minnesota School of Nursing – Dean
This is Connie Delaney, Dean University of Minnesota School of Nursing.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Connie. Latanya Sweeney? Okay, with that I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Welcome to our committee members. I was tempted to talk about how many meetings we've had, but I'm leery of doing so. Given the pace we're working at, I just don't want to remind people of how often we've been here.

We've continued at the Office of the National Coordinator and in HHS to work hard at the agenda that you have advised us on and that Congress has laid out for us, and this is an important milestone along that pathway. I know many of you have looked hard at the meaningful use notice of proposed rule-making, and your work was extremely helpful to the Department of Health and Human Services and to the federal government in designing that meaningful use paradigm. I know you have now had a chance to reflect on what was proposed, and your views will be extremely interesting I know to the Center for Medicare and Medicaid Services and to the Office of the National Coordinator in moving the rule to the next step, which will be its final form.

Of course, this is a rule that is likely to be revised again within a couple of years, so we want always to keep in mind that it is a dynamic rule, not something that will be set in stone, not even something that will be fixed for very long, and that gives you all an opportunity to come back here a few more times and work with us some more on the next version of it.

It's I think an historic rule for the field of HIT and perhaps even for healthcare generally. I've had the opportunity to meet with a number of colleagues from Europe who work on health information technology, and I think that the very concept of setting goals for the use of the technology rather than simply for its installation is a novel approach to policy-making in this realm, so your further advice has a chance to

perfect still further what I think is a very, very influential potential step forward in health information technology policy, not just here, but globally.

Having said that, I won't take any more time except to thank you again for being here. You all missed the excitement, most of you, last week. For a Bostonian it was an interesting sociological experience, and we continue to observe with interest how the city reacts to all this what used to be white (now it's mostly gray stuff) on the ground. With that I'm going to turn the microphone over to Paul Tang who really makes this thing run, and let him go over the agenda for the day.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, David. Before I forget I wanted to ask for a motion to approve the minutes which you had distributed to you as part of your package. Okay, second. All in favor? Opposed? Thank you.

To say that the agenda is jam-packed would be an understatement. I think David set up the discussion perfectly in the sense that this really is a very meaningful piece of legislation in the absence of health insurance reform. It may be one of our biggest movements in terms of improving the health outcomes of our country, so it's important work. A lot of people have put a super amount of time into this, and we really appreciate that.

Today we're going to hear from a number of the workgroups about their comments related to the meaningful use NPRM as well as the IFR. The meaningful use workgroup will start out with their comments and suggestions, recommendations, followed by the adoption certification workgroup which will talk about primarily the IFR with some implications for the meaningful use NPRM. Following lunch we'll have the information exchange workgroup that talks about the exchange issues, a lot concentrating on laboratory. Then privacy and security workgroup will talk about some of their recommendations pertaining to the privacy and security category of the meaningful use NPRM. Next, we'll have the NHIN workgroup providing some additional recommendations as they have in the past and conclude with the strategic plan workgroup updates to their recommendation for the ONC. Then conclude with public comments.

Any changes to the agenda? If not, then I think we'll begin with the first report which will be from the meaningful use workgroup. This is a workgroup that I share with George Hripcsak, and George is on the phone and donating his time, I believe, on vacation to this effort.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Hello.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Hi, George. Thanks for participating. We're going to go through a number of recommendations, twelve in all actually, and what I'd like to propose is that I will go through all of the recommendations first at a top level and then come back to them in clusters. Let's say four clusters, and then have discussion of those if that's okay with folks.

We'll begin with the first recommendation has to do with the progress notes documentation, and this is probably one of those things where, although we voted on every recommendation, it didn't even require a vote in this sense because everyone was very enthusiastic about reinstating this for a number of reasons, including those which you see on the screen. First of all, that progress notes are a very, very important piece of the documentation that should be in the medical record and certainly in an electronic medical record as well because it is important to the quality of care and to care coordination.

One of the points that was made in the NPRM was that it was a legal document, and so people would automatically have that in their EHR. The workgroup felt that that was not necessarily true. It is a very important piece, but it's also a difficult piece because it requires additional time to enter it in the record, yet it is very important. The other consideration is that if people do choose to split it out, to have some in electronic format and some on remaining on paper, then it turns out to not only split the record, but chances are you would lose all the information that was on paper going forward, and you would cause a hybrid system that not only is less safe, in other words more things fall through the cracks, but is very inefficient because you have to look at multiple places.

For a number of reasons, legibility, the quality and efficiency for making sure the record is complete, for avoiding hybrid systems, for being able to share information with patients, and to really, one of the main purposes of course of electronic health record systems and their communication interoperability is so that everyone who participates in the care of that individual can benefit from what's in there. Progress notes being that important, we feel it's fundamental to care coordination. The final piece that we listed was the ability of progress notes to share much more about the individual, the human side of care, than the structured notes that are commonly in EHRs.

Those are the reasons why the workgroup felt that progress notes are key, both to quality and the efficient use of EHRs that we recommend that be put back into the meaningful use criteria. That would be for the eligible professionals, and we'd have a strong signal that clinical documentation would be part of stage two requirements.

The next recommendation has to do with core measures. Core measures was a construct that actually the workgroup originally proposed back in July and October. Once we reviewed both the core measures that were proposed in the NPRM as well as the ones we've suggested, we found that neither of them quite measured up, so we've listed the attributes we considered as far as what would make a good core measure, and those were the following: 1) That it complied with the Institute of Medicine's six aims or other priorities such identified by the National Priorities Partnership. 2) Have an evidence-based link to improvement and outcomes. 3) Be hopefully measured using coded clinical information in EHR versus chart review. That would be to minimize the burden. 4) To be captured as a byproduct of care, so that's sufficient from a workload point of view. 5) That it applies to virtually all eligible providers, that being a critical component of being a core measure. 6) Finally, that we had a strong emphasis on measuring outcomes to the extent possible versus process measures.

When we look at the proposed core measures, we found that it didn't measure up according to these attributes, and for that reason we're suggesting that those core measures be removed as a mandatory part of the meaningful use criteria. That does not mean, however, that we don't support the notion of using HIT to support national health priorities. We do feel that national health priorities should be a key target for the HIT initiative, and in fact in the strategic planning draft recommendations you'll hear later this afternoon, that shows up again. The meaningful use workgroup is saying that it will come back and re-explore the notion of some shared health priorities as a basis for its meaningful use criteria.

The third recommendation was to reinstate the criteria that meaningful users stratify the quality reports by disparity variables. Clearly, the statute mentions this as a high priority, that is, looking at disparities in healthcare, and so this was one of the few criteria that addresses that, and so we thought it was important not to eliminate this one.

Fourth recommendation has to do with up-to-date lists, such as the problem list, the medication list, and medication allergies. In the NPRM it looked more like a one-time requirement that could be met as long as none of these lists was blank, but we felt that a large part of the value of EHRs and the clinical … in

these EHRs has to do with coded information in these lists, problems with meds, medications, allergies, so we recommended putting back in the up-to-date nature of these lists.

The fifth recommendation has to do with advance directives. There were a couple qualifications in the NPRM suggesting why they thought it might be removed, but when we look at it, especially for the Medicare population, this is one of the ways that we can honor the patient's request in end-of-life situations and one where the country isn't fully compliant. Our recommendation is to put that back in. One of the questions is that the advance directive itself or just the recording of the presence or absence, and right now, this would be the recording of the presence or absence for those 65 and older.

The sixth one has to do with patient's specific education resources. Engaging patients and their families is a very important category in meaningful use criteria, and this is an important piece of educating patients and giving them more information in order to help them make shared decisions about their care. Rather than just doing a Google search, for example, the workgroup felt that it was important that their provider, their healthcare team be able to endorse certain educational resources as important to them, and so that's the basis on which we'd recommend reinserting that.

The seventh has to do with clinical efficiency measures. There are a couple administrative efficiency measures in the NPRM. One of the objectives is to have clinical efficiencies, and two of the ones that we had recommended in the original proposal had to do with pharmaceuticals, namely generic prescribing and the other with high-cost imaging tests. We still found that that would be an area of great importance in terms of controlling the cost of healthcare, and so recommended the reinsertion of a requirement that eligible professionals report on the percent of medications entered into an EHR as a generic formulation when those options exist in a relevant drug class. The way we incorporated diagnostic testing was to suggest that CMS explicitly require at least one of the five clinical decision rules to address efficient diagnostic test ordering.

The eighth recommendation has to do with the timing. Basically, both the providers and the vendors of these products need time in order to develop, test, and implement new functionality. Although the NPRM states that I think it's by December of the year before each stage they would be publishing the NPRMs for the subsequent stage, the workgroup is recommending to give as much advance notice as possible in order to signal and give both the developers time to produce products and the provider organizations time to implement them.

The ninth recommendation is a simple one, but it focuses on a very important piece of meaningful use criteria which is CPOE. Because that is so instrumental in producing the quality benefits of using EHR, we wanted to make sure that the intent was that the authorizing provider be entering the orders rather than someone entering it on behalf of the provider.

The tenth has to do with reminders, and I think there may have been a miscommunication in terms of what our intent was. Our intent was that patients would receive reminders that are appropriate to them, and typically, that would be across all demographic characteristics, such as age and sex, and in the NPRM it talked only about patients over 50 years old and sort of doing a survey and making sure 50% of people over 50 years old received some kind of reminder. Our intent was that anyone receive reminders appropriate to their needs, and so what we're proposing here is that for each specialty area that they go ahead and choose a relevant preventive health service or followup reminder and implement that. All the denominators would be all patients who were potentially eligible for that reminder who had not received that service.

The eleventh has to do a clarification as well. We had introduced the term relevant encounters without precisely defining that, so in fact, in this recommendation we're trying to hone in on just transition of care and delete the relevant encounter concept. Transition of care we're defining as being going from one setting of care to another and a setting being a hospital, ambulatory primary care practice, or ambulatory specialty care practice, long-term care, home health. When they make that transition from one of those settings, that's when we're invoking the medication reconciliation or clinical summary criteria.

Finally, saving the best for last is the flexibility. I'm sure all of us have heard about the desire to have more flexibility in some of these criteria. At the same time of course the meaningful use workgroup and the committee at large felt that there are a number of things that need to be in a sense mandatory in order for the country to derive the benefits that we're expecting, but to answer the question about flexibility, we've proposed the following.

One is the idea of the all or nothing approach. If an organization in good faith pursues all of them and for some reason can fall short in let's say one, that would prevent them from qualifying for the incentive. It's hard to anticipate all the things that go on in the local situation, and so there may very well be, and you can't even predict which one of the criteria may be particularly challenging for a particular group. For that reason we wanted to try to build in some flexibility in not achieving the full status at a particular point in time. The intent was that we give some flexibility in terms of deferring the completion of criteria to stage two, but not the elimination. In a sense everything is mandatory, but we're recommending that a small number, something like approximately 20%, would be deferred until the next stage.

That sort of permits flexibility, yet while preserving a floor. George Hripcsak came up with this idea. I think he travels a lot like me, and so 311 is sort of emblazoned in our head, so this is the 31110 approach which is that you know that we have five categories of meaningful use criteria, and so we would propose that in category one, which has the largest number of requirements, that an organization could defer up to three criteria for the stage one and subsequently in the next three one of each, but there's no deferral at all in the privacy and security category for obvious reason. They would also be required to comply with all of the quality reporting measures.

That's what's on the table for this particular recommendation. Let me provide a little table that may be a little bit further explanatory. There's the 31110 approach. Now, on the right there are some things that are sort of a floor, and one might even think of this as sort of the 311 floor of mandatory. We have essentially a mandatory floor, a large number from which you can choose from but are permitted to defer up to 31110 of the criteria, and I'll try to explain it a little bit better when we come back to discussing it further.

Those are the 12 recommendations from the meaningful use workgroup. Let me open up for the first cluster of discussion, the first four recommendations. Judy.

Judy Faulkner – Epic Systems – Founder
If you could explain a little bit more, please, Paul. When you say progress notes, what are you thinking of as progress notes?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The progress notes are the notes entered in by the clinicians as part of the individual's care. In the outpatient setting, it's much more physician progress notes. In the inpatient section, it'd be the physician and the nurses typically.

Judy Faulkner – Epic Systems – Founder
I'm thinking of the EMR. I'm thinking of all different things. There are structured checklists. Is that a progress note in your mind?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's a good question. I don't think we went to that level of detail.

Judy Faulkner – Epic Systems – Founder
I'm wondering if there's a wide variety of ways we can define progress notes so that when somebody uses a structured checklist instead of text because you do have text as one of the bullets that there may be just all sorts of ways. It could be a drawing with some stuff on it. Is that a progress note if you're in ophthalmology?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Those are good questions. I think the progress note, some people do use checklists in lieu of let's say a dictated note or a written note, and those would be included in the progress notes section.

Judy Faulkner – Epic Systems – Founder
You're saying the intent is that it's flexible then, that there may different ways of, say, the progress note—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The intent is that it's flexible in that it would be those things generally considered as part of the progress note. Where I thought you were going is there are sometimes people have questionnaires that may be supplemental, and I can see how that would be gray areas. If anybody else from the workgroup wants to comment, Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I think the point was to try to signal that we wanted clinical documentation in the system and to eliminate those transition kind of situations where people are actually keeping paper records in parallel with their electronic health records and that the information isn't complete in the electronic health record because there's also another paper record that's operating side-by-side. All of those are the things that we were trying to signal away from so that the clinical documentation would be contained within the electronic health record.

Judy Faulkner – Epic Systems – Founder
As it becomes final, it might help people if you explain that there can be different ways to do the clinical documentation.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good, thanks, Judy. Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research
On the same topic in our interim final rule I don't believe we have any certification criteria specifically focused on progress notes. I guess one question I have is, and I'm hearing this desire for some flexibility here as not necessarily a standard, but at least some capability whether it would be something that would typically be in an EHR, a capability that would be built into EHR already. If in fact we consider this recommendation for meaningful use, we might need to consider for the IFR to parallel that because obviously we can't require folks to document progress notes if their certified EHR doesn't have that capability built in. That's what I'm asking if there's any ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Procedurally, I don't know how we'd handle that. Paul, did you have something?

Paul Egerman – eScription – CEO
Yes, just a couple comments. First, I think Judy's comment is very important. I think especially on the ambulatory, the outpatient side, if you advocate progress notes, you have to be clear that that does not necessarily mean free text. There's a range of what a progress note might be.

Then to pick up on Jodi saying, yes, if you put this in the NPRM, I think you do have to have certification criteria to make sure that you can have these progress notes in the record. Then you probably need certification criteria for some interfaces so that people can get textural information from external sources into the record, too, because otherwise, you're stuck with a situation where the physician is expected to type in the progress note as opposed to having a transcription service type it in and import it. That's an observation.

The other observation I have is whether or not you considered a separation between the ambulatory and the inpatient sites because the progress note really has a totally different function on the inpatient side, and it's bit harder to automate because there's a lot of workflow issues. In other words, the progress note on the inpatient side can frequently be important five minutes after its written, where on the ambulatory side that is much less likely.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Actually, with regard to the latter point, Paul, that's why in progress notes for inpatient setting was not included in stage one even in the …--

Paul Egerman – eScription – CEO
It's not, okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
--original recommendation. Other comments in the first four recommendations?

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, please.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
This is George.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Hi, George.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Also, in answer to Judy, I think the intent was that outpatients, the ambulatory progress notes is that thing which … as a legal document of the clinical encounter between the provider and the patient. That was kind of what was in mind. I think the mention of free text, we think it's important, and I think it's more to avoid setting a rule that … note has to be structured rather than at this point saying the note has to be in text.

Marc Probst – Intermountain Healthcare – CIO
On number four, and I agree by the way with everything said about the progress notes, but on number four, is that more ambulatory focused, or is that unique across hospitals then, the ambulatory setting?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It was intended to be on both sides.

Marc Probst – Intermountain Healthcare – CIO
Okay, I think there are challenges on the hospital side, very large challenges associated with that, and you might look at some way to phase that in.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Clarifying question, one of the four requirements for stage one according to proposed meaningful use amendments that you've put forth is CPOE use. I'm wondering what the basic data requirements are for CPOE and whether they have implications for the floor requirements in the quality, safety, and efficiency domain.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's a good question, David, and in a sense this is how we spent a lot of our time trying to struggle over the flexibility. Originally, that's how we built the meaningful use criteria. They all sort of played off and were dependent upon each other, so we felt that all of them were "mandatory."

It is our attempt to acknowledge that there are some things that may be particularly challenging of the let's say 25 criteria for eligible professionals where we tried to give some flexibility. Yet, all of them do depend on each other. For example, what you just mentioned in CPOE, clearly having up-to-date medication lists and medication allergy lists and even problem lists are very crucial to CPOE and the clinical physician support.

The intent is that everyone be working on all the criteria, but if for some unforeseen circumstance causes to either miss the full completion of an area, we didn't want you to be penalized by not getting any of the incentive. That was sort of the thought behind the recommendation 12, but you're right to say that a lot of these things need to be, ideally, all these things would be completed in order to get to the benefits of EHR. Any further comments on the first four? I'm sorry, Judy.

Judy Faulkner – Epic Systems – Founder
On the third one and this may be a stupid question, but I'd like to ask it. The race/ethnicity, do people typically collect both race and ethnicity, or is typically race and/or ethnicity?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
In order to both measure and understand and address disparities in care, it's important to record and address both areas, both race and ethnicity. Many of the states, California's one of them that does require to … both. These are things that CDC as an example and CHS require for part of their statistics in order to understand how healthcare's delivered in the country.

Judy Faulkner – Epic Systems – Founder
Do systems typically collect both right now?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I believe. I don't know whether 100% do, but certainly some do.

Judy Faulkner – Epic Systems – Founder
Here's a really stupid question then. Is, for example, Canadian ethnicity?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's a nationality.

Judy Faulkner – Epic Systems – Founder
Nationality, okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other questions? Larry Wolf.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
This is a small comment, but I see it, so I thread to some of the other comments …. Presumably, an individual could say I don't want to tell you something, and they're not telling you could count as an answer. Is that the thinking around meeting the criteria that if they say, "I don't want to tell you" that that counts as an answer to the question?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
My interpretation, and I'll open to other people's thoughts, my interpretation would be yes that that would count. There should be a code that says declined to state. Marc.

Marc Probst – Intermountain Healthcare – CIO
In this specific point, and we're talking primarily about electronic health records, this data's likely not collected at the electronic health record. It's likely collected in a billing system that would then be interfaced into it. Is that going to be okay that that exists in a billing system versus the EHR itself, or does it need to flow into EHR?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think a lot of the certifying criteria, and Paul can correct me if I'm wrong, has to do with the data getting into the EHR, and one of the reasons for this particular criteria is that you want to be able to report on your outcome measures stratified by disparity variables. It eventually has to make it into whatever systems you use to report on. The good side of that is I agree exactly what the outcomes going to be. The bad side is there is a lot of work. It isn't a simple field being added to a system. There's going to be additional work associated with fulfilling this. Yes, a lot of it's workflow, and many states have already required that and …. Paul?

Paul Egerman – eScription – CEO
To respond to that comment, to me it's not clear where the data needs to reside. Perhaps the billing system is part of the EHR. I'm not sure as I read it whether or not if you had it in the billing system whether or not that qualifies. I think that you need some clarification to that.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I think the point is in the reporting you have to be able to stratify your reports in order to look for disparities in your delivery system, and so whether or not that's done through an interface or the information is entered in the billing system and transferred over, I don't think we really need to specify

that. I think it's really, the goal here is that people are able to report quality outcomes and process measures by race, ethnicity, and language.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I'll talk about the other side, too, the efferent arm. It's one thing to report and understand how you're addressing the various patient population groups, but it's the other to do something about it. For that reason, like clinical decision support, the EHR at least has to have access to that information. Regardless of where it's captured, and it's very well at the registration area, it needs to be present both to report, but more importantly for us to make sure we address any issues that are related to those variables at the point of care. I think my point was primarily around, some of these changes although appear to be fairly straightforward, they do have a significant trickle through amount of work, whether that's workflow or actual interfaces or changes to databases, that type of thing.

Neil Calman – Institute for Family Health – President & Cofounder
Absolutely.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's our belief that that's required and necessary, though. Other comments on the first four? Let's move to the next four then, please. That would be five through eight. That's the advanced directives, the patient specific education, the clinical efficiency measures, and the glide path. Charles.

Charles Kennedy – WellPoint – VP for Health IT
Yes, on your recommendation number seven, I think including generic utilization rate is great. Most e-Prescribing vendors can also produce a formulated adherence metric which is also valuable in terms of cost of pharmaceuticals, and I didn't know if the group considered like a drug-drug interaction alert type of report. I know there's a lot of work that still needs to be done in terms of optimizing those and physicians' response to those. On the other hand, ambulatory adverse drug events represent a significant cost and safety issue.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's a good, Deven, you're looking like you're going to respond ….

Deven McGraw – Center for Democracy & Technology – Director
The information exchange workgroup had a hearing fairly recently on e-Prescribing, and that issue was mentioned by a number of persons who testified to us. I think we have that on a list for maybe some development of some longer term recommendations. We didn't think we could sort of process that and put forth something concrete in time for this process, but it's definitely an issue.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. Judy.

Judy Faulkner – Epic Systems – Founder
Just in reading it, I'm not sure whether it means when it says percent of all medications entered into EHR as a generic formulation. Are you talking about percent that's in the formulary or percent that's ordered by the physicians?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's the percent that's ordered by the authorizing provider. It doesn't always have to be physicians.

Judy Faulkner – Epic Systems – Founder

Okay, because I think this could be read as, maybe I'm wrong, as percent of medications entered into the EHR ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Maybe the word should be ordered instead of entered.

Judy Faulkner – Epic Systems – Founder
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
So that would be one clarification. The other clarification, and we may not have the words correct, but the idea is not that you just order the generic word for a trade name drug. The idea is if there are suitable generics available in a drug class, then you would choose the generic formulation, or that's what you'd report on, recognizing that that is one of the high-cost issues in medical care.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I have a question. When you recommend that these measures be added back in, are you adding them back into the flexible category or the floor, or do you need to designate what you're adding them into?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We weren't designating, and these two in particular weren't part of our proposed floor. Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Just in response to what you said, Charles. The question about the drug-drug and the drug formulary information is contained in another area of the metrics. This particular metric around generic drugs was about efficiency and cost, but I think that's contained in the earlier section of the table.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Are there other comments? Marc.

Marc Probst – Intermountain Healthcare – CIO
Yes, well, if we're on number seven, we'll stay there. The focus then is on the prescription drugs, but there seems to be an awful lot of other clinical efficiencies. We're just saying that that's broad open. You can go with that, but we want to make sure that at least one of those that are focused on is prescription medication and the use of generics.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Correct, a couple high cost areas in healthcare are drugs and high-cost imaging which is why we originally chose those for clinical efficiency, and so we're just trying to reintroduce them.

Marc Probst – Intermountain Healthcare – CIO
Then on number six, patient-specific education, I think the question, and you probably know the answer I think when I read through the document, but how do you really measure that that the clinical education's being done, the patient-specific education is being completed?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
In many EHRs when you "prescribe or administer patient education materials," that act can be documented. For example, if it is included in some kind of patient instructional or education materials, you can document the fact that that occurred.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Or it could be ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, but it'd also be something that we could have someone self-attest so they would have a checkbox on there that said we provided that education versus having it be generated by the system. That would qualify as well.

Marc Probst – Intermountain Healthcare – CIO
Okay, thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any other comments on that cluster? Okay, let me do three more before we get to our flexibility recommendation, so nine through eleven. Nine is just clarifying that the CPOE is intended to have the orders directly entered by the authorizing provider. Ten was patient-specific prevention and followup reminders, and 11 was to clarify the transition of care. Marc.

Marc Probst – Intermountain Healthcare – CIO
I have one on nine, and I guess it really goes down to what an authorized provider is. One example would be in our intensive care units, we really use pharmacists as the ordering provider, so they're there with the physician going through the intensive medicine units, and it's been a very effective workflow, so would pharmacists be an authorized provider or an ordering provider?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I suppose if they are in your state, so pharmacists can order prescriptions in your state?

Marc Probst – Intermountain Healthcare – CIO
I think that really goes to what is an authorized provider and specifying that because there are workflows that are embedded right now that allow for this type of order entry outside of just a physician.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I'll just give you a personal opinion. The intent is to be able to present information, let's say through clinical decision support to the person making the decision about in this case medications relevant to this patient's care. If that is truly the pharmacist and that person is allowed, then that seems like that would qualify. If it's someone acting as a scribe, I think it would not. That actually goes to the point we were trying to avoid. Even though you may be permitted to write a prescription in a state, if you're not the primary decision-maker, then that wouldn't qualify under our intent anyway. Do you see the …?

Marc Probst – Intermountain Healthcare – CIO
I see the difference, but in the instance that I'm talking about, the primary decision-maker would be the pharmacist working with the physician on that patient, so pharmacist having the greater knowledge about the drugs that are in use making that decision with the physician.

Judy Faulkner – Epic Systems – Founder
Follow up from that to I think a lot of our academics, the residents and the students, are the ones who order it, tee it up. They may get it then, the authorizing provider may send it out in the end, but they are basically ordered by the residents and the med students, and sometimes the residents and the med students actually place the order. I don't know how it's going to work in the academic environments.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It's pretty clear that the residents would qualify, but it's also pretty clear that the students who are not licensed professionals, they may—

Judy Faulkner – Epic Systems – Founder
But they're going to have to have the au—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's correct.

Judy Faulkner – Epic Systems – Founder
But is it okay, if they order it, it's put into a holding, and then the authorizing provider signs it. Is that still okay because the authorizing provider wasn't the one who got the drug-drug interaction for example? It's going to be the—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's an interesting loophole, but the intent is that the person who is authorizing it, making the decision, should get the feedback, but I think you've uncovered a loophole in the way the systems work. Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Yes, I think this is an important enough loophole that we should table it and address it because that is a workflow that does happen, and I think you're absolutely right. You want those decision supports to appear. It's okay if they appear for the resident, but they also should appear for the person who's authorizing that or co-signing that. There are a number of circumstances where orders are entered by other people, but it's in the review of those orders. I'm sure we would want to have the systems be able to present the decision supports at that point as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
In other words that doesn't meet the intent, so the intent was to get feedback to the person approving that patient care decision. We'll have to address as Neil said the fact that systems probably currently do not give that additional feedback, nor do the providers necessarily want to see that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So it is a problem. Every academic health center is not the same, but as a practical matter, the residents entering the orders are licensed physicians who have the authority to change the order in response to clinical decision support. Now, it's also true that sometimes there's an attending who will countermand or override the president's recommendation or specify what the order should be. Nevertheless, if someone gets feedback that the patient's allergic to that or there's a fatal drug-drug interaction or if there's some other decision support, the dose is wrong for renal failure or the dose is wrong for another counter-indicating condition, it adds work for the resident, but the resident has the authority not to enter that order and the knowledge not to enter that order. I think that is not a problematic situation. The medical student is a somewhat more problematic situation.

Judy Faulkner – Epic Systems – Founder
--a terminology thing there that, I'm not sure. Who is the authorizing provider in that academic environment, especially for billing purposes? Are we using one term differently for billing and another for this? Is the authorizing provider going to be the attending and not the resident, even though the resident is in another sense totally authorized?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

The licensed professional responsible and accountable for the clinical decisions would be the authorizing provider. In the resident's case, that person is licensed and responsible as David just mentioned. In the student's case, that person is neither licensed nor responsible.

Judy Faulkner – Epic Systems – Founder
Right, I understand.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
… responsible from ultimate medical legal point of view. Please, Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
A small additional comment at the risk of introducing more complexity into accounting here that in cases where the primary provider is not entering the order, it might be useful to track who did and what the reason was. For example, was this a copy off of a handwritten order, or was this a telephone order? If it was, was there decision support involved because it could've been I'm on the phone and I'm entering the order and I'm relaying the decision support information I'm getting to the provider, or they gave it to me over the phone. I scribbled it down. I keyed it in, and I was just acting as a clerk in that ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We're saying those examples do not count in this ….

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
I understand that those don't count, but I'm asking as we look to learn how the systems are actually used that that might be a place where it would in fact be useful to know the actions that are happening.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle.

Gayle Harrell – Florida – Former State Legislator
I'm not sure Judy's question was totally answered, especially in a situation in an academic setting when you have a resident. For billing services you'd be attending is the one, especially for our friends at Medicare. A resident cannot be a billing agent. It has to be in the name of the attending, so your question is still not answered as to really who is the authorized individual at that situation.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think Judy asked two questions—who's the authorizing provider and who is the billing provider. What we're shooting for is for the orders to be entered by an authorized provider accountable and responsible for that patient's care. As you point out in the academic setting, that may be different from the billing provider.

Gayle Harrell – Florida – Former State Legislator
Okay.

Judy Faulkner – Epic Systems – Founder
… was to clarify it in the terminology so that there isn't any confusion as to what it means.

Gayle Harrell – Florida – Former State Legislator
Exactly, and also then you get down to liability issues as well. The individual seeing that alert and if you have an attending having seen that alert, is the intent to have the attending see the alert as well as that authorized resident see the alert, or is it not? I think that needs to be clarified as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It was not intended in the teaching situation that the attending would necessarily see the alert. The person who is the licensed professional who is authorized and responsible for that individual care decision is the resident who wrote and entered that order. Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Just to clarify, you're using I guess a California example. In New York state residents are not licensed. All international medical graduates have to complete three years of residency before they're eligible for licensure, so there's a completely different sort of process in New York. I just think that's why it's important that we sort of stick with what we're trying to accomplish, and I don't think we should get this confused with sort of licensure issue because then decision-makers have the opportunity to see decision support.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good point. The state jurisdiction won't—

Neil Calman – Institute for Family Health – President & Cofounder
Won't leave this alone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Will complicate many things, yes. Other comments about this cluster?

Judy Faulkner – Epic Systems – Founder
What is the … this one?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil's proposal was that we stick with the term authorizing provider if I'm understanding correctly and try to do a better job of defining what we mean. The resident, even the state of New York, is the authorizing provider. My understanding is the technical point is that person's not licensed, but that person probably is responsible and accountable for those orders that are written. Is that correct, Neil?

Neil Calman – Institute for Family Health – President & Cofounder
Yes, I guess my point was really that I guess it's part of the whole teaching process. We do this for a lot of things. We delegate the ability for residents to do examinations and to do procedures and to do other things, but they're done under the authority of the attending physician, so I have no problem with the residents being presented with the decision support if they're the ones who are entering the information because, again, it's part of the delegation and supervision process that goes on as a normal part of these teaching environments. I think if we clarify that we could stay away from the billing and licensing and other things like that and really just sort of address it that what we're interested in is that the people who are actually entering the orders and have the decision-making authority have the opportunity to be presented with the decision supports.

Judy Faulkner – Epic Systems – Founder
Neil, when you say people who are entering have that opportunity, if the residents are entering, they will have that opportunity. If the attendant isn't entering, typically the attending doesn't get that opportunity. Are you okay with that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Yes, what I was trying to imply is that that's really part of the entire teaching environment, right? We do that for everything. The attending doesn't necessarily repeat the entire physical exam or go through all of the medical history all over again, and so part of the teaching supervision would be some understanding now in this electronic environment that when residents are faced with the decision support how they respond to them appropriately and that, of course, the attending remains the person responsible for those decisions made by the residents that are being supervised by them.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, sir.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
This is George. One of the intents was to avoid the unintended consequence of encouraging less efficient and less space workflows in practices or hospitals for the sake of achieving meaningful use. We don't want people setting something up to get the orders in so you can get your meaningful use criteria when under the old system you would've entered that order yourself.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Marc.

Marc Probst – Intermountain Healthcare – CIO
In this whole conversation, and I know no one does verbal orders and has nurses enter those orders, but if that were to happen anywhere, how would that be authorized, or how would that be an authorizing provider since, like in New York, the residents really aren't licensed either?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil, you want to take that one?

Neil Calman – Institute for Family Health – President & Cofounder
I think we should bring this up in our next … meeting.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Probably. Originally, the thought would be that verbal orders do have to be countersigned by the …. That's one point. The authorizing provider then of course would not be faced with the CDS alert. That's the loophole in that scenario. I think we need to go back and try to at least be more precise, even though we can't be perfect in terms of considering every definition in every state, but we need to be more precise on how we define this term, but the rationale is what I shared with you. It is so that the system can provide the appropriate information to the person making that decision about this patient's care, and we'll try to do the best we can. Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I would just make the same point about nursing that we made about residents. Nurses are licensed professionals. They function in a workflow that's been designated in institutions about how verbal orders are taken, recorded, and everything else. If part of that process then has to be that as people are entering those orders there are decision supports and alerts that come up, that those get reported back to the person who is issuing the orders. Yes, I think that these things are going to become built into the way work is done within institutions, maybe in ways that are different, but I don't think we want to start removing some of those professional relationships and building additional layers into them because I

think we will end up making the systems less efficient, and I think that would be counterproductive to what we're trying to accomplish here. We're trying to make them safer, but not less efficient at the same time.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Paul, this is Latanya.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Hi.

Latanya Sweeney – Laboratory for International Data Privacy – Director
What I'm hearing is kind of pushback not only in terms of methods, but also the pushback in terms of the accountability issue. That is I hear the recommendation being very squirrely on holding the "authorizing provider" responsible and making sure they're the person who gets the feedback, but I would have you consider is that going to be at the expense of the workflow which is I think what Neil was really pushing back on.

David Blumenthal – Department of HHS – National Coordinator for Health IT
This is David Blumenthal. I don't think we should lose site of the fact that the adoption of electronic health records is an evolutionary process and that you can't fix every flaw in the healthcare system through the means of an electronic health record. I'm sorry if I misled you on that, but part of what we're identifying here in this discussion is the fact that medical care in many cases is or should be delivered by teams of people rather than by individuals and that the delegation of responsibility within a team varies.

We've seized on academic health centers because that's most clearly where teams do occur, teams of attendings, residents, nurses, often pharmacists, physical therapists, respiratory therapists. They're all present and working around a patient's bed at the same time. That's a complicated environment, but it will almost certainly be improved by the injection of decision support into that environment by whoever has the responsibility of entering the order at a given time, so to try to be excruciatingly precise is in a sense trying to fix a part of the system doesn't fall to electronic health records to fix.

The burden of the electronic health record is to make the decision better which it inarguably will do if it injects decision support into that mix. Now, whether it injects it at precisely the right spot in the first instance when it's introduced, I think there's legitimate debate, but I think the system will learn over time who to use that decision support optimally.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very wise counsel, well said. Marc.

Marc Probst – Intermountain Healthcare – CIO
Yes, on that note, Dr. Blumenthal, I think decision support doesn't just happen at POE at the time of order. Decision support happens in the pharmacy when the pharmacist is fulfilling a prescription, or it could happen in a radiology environment, or it can even happen when the drug is administered and you do bar-coded medical administration. There's a whole flow of decision support built in there, and everything's not going to need to happen right there at the point of entry.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Anything else? Okay, we're going to get to recommendation 12 now, right? Let me try to set it up a little bit better. One is that we are assuming that everybody in good faith is going to try to meet, Judy. …

Judy Faulkner – Epic Systems – Founder

Question about—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
…

Judy Faulkner – Epic Systems – Founder
Yes, a lot of preventive health services are outside of, anyway, ten may be a difficult one. In the knowledge, how does that knowledge get there?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
To clarify ten, one, the individual organization picks what's relevant to them. It can be a preventive health service, or it can be followup reminders and then decide what percent of patients who are eligible for that reminder were reminded. That's different from saying, well, that's self-explanatory.

Judy Faulkner – Epic Systems – Founder
I think for certain things, smoking prevention for example, that would be easy. There may be a lot that are much more elusive.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You get to choose, so the hospital or the—

Judy Faulkner – Epic Systems – Founder
Okay, so when it says for a chosen, it means they choose?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
They choose, correct.

Judy Faulkner – Epic Systems – Founder
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We're trying to give them the flexibility because, again, each organization, geographic area, ethnic patient population has their own local priorities, and we want to respect that, but we want them to use this tool in order for them to do a better job.

Judy Faulkner – Epic Systems – Founder
Okay, wasn't sure who was choosing.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, sorry.

Judy Faulkner – Epic Systems – Founder
Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We ready to move onto 12 then? Twelve is the flexibility recommendation. We're assuming that all of the eligible professionals and hospitals will be in good faith working on all of the requirements; however, there may be individual circumstances that are local or constraints with either their medical staff or EHR that may prevent them from not meeting the exact target. For example, some of the thresholds are 80%, some are 50%. If they come in at 79%, it would be hard to say if they tried in good faith to meet them all

that they should not receive any of the incentive money, so that's the reason or rationale (we've certainly heard that from feedback from the public) that we're recommending that we give some flexibility to the all-or-nothing approach.

Yet, because we recommended these in the first place, we felt that the vast majority are fundamental, foundational to achieving the benefits we are expecting from EHR systems and their meaningful use. The approach was to allow some flexibility in a small number of the criteria, and it's defined as deferring. Let me point that out, too. This is not forever getting a …. It is to defer the fulfillment of a small number of meaningful use criteria from stage one to stage two.

The proposal on the floor is that an organization may defer up to three in the first domain (the quality domain), one in the patient family engagement domain, one in the care coordination domain, and one in the population public health domain. That's the maximum. That's not the ultimate …. That there be no deferrals of anything from the privacy and security domain, and there's no deferral of any of the clinical quality measures reporting.

I think what we'd like to do is get the sense of the full committee on the number of options. One is do you agree with the need for flexibility from the all-or-nothing approach. Two, if so do you support the 31110 approach in terms of the deferral maximum? Then the third one I'll discuss later to see how we make with the first two is whether there should be floor that are required at all. In other words, you cannot defer any of a small number. Let me try the first one which is do you believe we should pursue a flexibility approach versus the all-or-none? Charles, we'll go around.

Charles Kennedy – WellPoint – VP for Health IT
This comment probably comes from the fact that I'm sitting next to Tony, but while I applaud the notion of flexibility, I worry about the complexity of this and the communication associated with it. A lot of the times when we pay physicians as a health plan, a lot of the issues arise from the complexity of the payment rules which leads to calls of a lack of transparency and other things. I appreciate the intent. I worry a lot about operationalizing this and the communication of it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Very fair. Thank you, Charles. We have the private and public sector payers speaking. Gayle.

Gayle Harrell – Florida – Former State Legislator
Well, I certainly am on the opposite side being more on the provider side, the recipient of perhaps the payers, and I believe, and also on the patient perspective. I think that we set such a high bar when we started out on this mission, and I was one of those that sat here at this table and said that the proposal that was on the table was extremely aggressive if you'll remember my comments, Paul, and I was one of those people, the voice out there saying that we needed to really not be so aggressive. I found as we went through the whole process there have been lots of my considerations taken into effect.

I want to commend you greatly on this flexibility. I think we need more flexibility instead of less flexibility. In fact, I think the 100% is very difficult. You're setting a standard that is so high, very few providers will meet it, and we will then really do something I'm very afraid of is not have the adoption of electronic health records, and we will stand in the way of the goal that we are all trying to accomplish. I absolutely commend you. I would give more flexibility. The only thing that I am absolutely adamant about no flexibility is privacy and security.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Deven.

Deven McGraw – Center for Democracy & Technology – Director
I think these were some very difficult discussions that we engaged in as a workgroup because on the one hand I think we all inherently want the providers to have incentives to take the funding, get the technology, and start exchanging the data. Yet, if there was full flexibility, there are some sort of core pieces that if they don't get done won't necessarily move us closer to the goal of using health IT to improve care. One of the things that I got comfortable with in this particular approach is this notion that it's not optional. It's deferred, and in fact, if you have to be meeting all of them by stage two, you kind of have to be working on them during stage one even if you're not necessarily measured on all of them.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Marc.

Marc Probst – Intermountain Healthcare – CIO
Yes, I think we have to have a very good definition of what meaningful use is over all the stages and understand where we're going, but having some flexibility in arriving there is going to make this a lot more achievable, so yes, I'm very supportive of flexibility.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Christine.

Christine Bechtel – National Partnership for Women & Families – VP
I echo Deven's comments very much. I think this was a difficult thing for me to think through anyway because I want to reinforce the idea that the signals in the draft rule are very strong, very clear, and directionally very sound, but I understand the need to balance forward progress with achievability.

That being said I have a couple of comments, but I'll only make one in this part of the discussion, and that is, Paul, to your characterization that in good faith we expect people to be working on all of these. I don't feel that that's an accurate characterization of this particular approach unless there's something that I'm not understanding. If we're allowing people to defer, I think in fact it does mean they're not going to be working on the criteria until some later point, and I take Deven's point very well. If it was the case of you're working on everything, but we're going to allow you not to achieve a threshold, I think that's actually materially different in my understanding which is to say 100% of the requirements would be preserved and required, but you could miss some targets, and I think that's materially different from you can defer some criteria. If I've gotten that wrong, let me know, but I just want to make sure that we're very clear on that.

The other quick thing that I'll point is some concern, and I'd be very curious what other folks think about the idea of actually breaking down the 31110 in privacy and security which I completely agree with, but breaking them down as opposed to saying you can miss six in total, you can defer six total would actually force people to or could have the practical implication or impact of allowing folks to say, well, in care coordination where there aren't a whole lot of requirements, I'm not going to do one there as opposed to maybe choosing a priority in another area, again, recognizing the mandatory. I'm not sure if that was completely clear, but there you have it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Not sure. David.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Well, I want to make a point for the record here which is that I'm in effect not sharing this portion of the meeting because I can't. I'm listening carefully. Tony is listening carefully, I'm sure, even though he's talking on the side with the other payer in the room, and we're all listening. I'm asking questions to clarify my understanding rather than to indicate a point of view. I find this discussion extremely enlightening and valuable, and I'm sure we're going to take it into account. I did want to ask Christine if she could elaborate for us on the difference between deferring and trying but failing. If you try and fail, let's say you try and you fail completely, so you have 0% compliance, is that different from deferring? In effect as a practical matter for Tony's purposes, measuring the difference between deferring and failing, I'm not sure that there is a practical difference.

Christine Bechtel – National Partnership for Women & Families – VP
I think it depends on which criteria you're talking about. For example, if one of the ones that you deferred was test the ability to exchange key clinical information, that is a pass/fail think. You can do it or you can't, but a number of the criteria, actually, have thresholds associated with them. The difference to me is about saying you have to report a quality measure, and the threshold is 80%. Then if you defer it, you don't actually have to report it. You don't actually have to start doing it whereas if you miss the mark it is I hit 70% versus 80%, but I was doing the workflow changes and the implementation necessary to actually be working on those criteria. I just didn't perform to the level required in the rule.

David Blumenthal – Department of HHS – National Coordinator for Health IT
But in order to be meaningful user in that circumstance, aren't you in effect just lowering threshold from a practical standpoint?

Christine Bechtel – National Partnership for Women & Families – VP
Yes, but you're still requiring that the workflow change and the resource investment goes into being, developing that ability and incorporating it in your care process from day one as opposed to saying I don't have to start working on that now. I'll start doing that later.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You would ask them to attest to working on it rather than to demonstrate that they've met some quantitative goal.

Christine Bechtel – National Partnership for Women & Families – VP
Yes, I think I'm pointing out a key, this is just a key difference in the approach. In the approach that I think I'm hearing described and that the workgroup talked about is about complete deferral, allowing complete deferral of beginning to work on some criteria as opposed to just missing a threshold, but you're attesting that you've already begun working on that, and I just want to be clear about that difference.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Deven.

Deven McGraw – Center for Democracy & Technology – Director
I think I get the intent of saying that we want to eligible providers and hospitals to really try hard to get to all of these and then giving them a mulligan or a pass on some number of them that they don't hit. I'm not sure, though, that I necessarily see the distinction at the end of the day because if in fact you've got two years to hit the stage one criteria and in stage two you have to be hitting them all at 100%, you don't really have a choice not to try at least by year two of stage one or you won't hit it sufficiently at stage two to keep getting the financial incentive. In some respects I get it from an intent perspective. I'm not sure based on the way we would want to structure this I think or that I would want to structure at least that it necessarily makes as much as a difference as one would think.

Christine Bechtel – National Partnership for Women & Families – VP
Right, and you're raising the deferral issue, and that's what I'm pointing to is for that first year in particular, it is pertinent. I just want to be clear that it is permissible to in fact not work on something, but you will have to do it later, and that's the nature of deferral as opposed to saying everybody's making a good faith effort to do everything from day one, and in that first year, that has the impact. I just want to clarify the distinction, but I hear you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I want to make sure we get enough time for this other half of the table to have a say. Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Having been part of this what seemed like endless discussion over the past two weeks with hundreds of emails going back and forth, I think we've come to a point that I feel comfortable with. I think there's one piece, though, in the discussion that we probably need to be cognizant of and that is that it's not clear what's going to happen yet in phase two. In phase two my understanding is we'll actually be, in other words for the 2013 criteria, in fact there may be new requirements. I would imagine there will be new requirements, that we're not just saying that in 2013 we're going to take the 311 and eliminate it and now you're going to have to do everything. There may in fact and I would imagine be a set of new requirements, and maybe there'll be another 311 for what those requirements are, but I think one thing we do want to signal is that we do expect that none of these are going to go away. It's not a matter of taking a pass and then hoping that one of these will somehow not show up in the 2013 criteria, but I think we're about as close to a middle ground as we can get, and I think it's absolutely critical that there be some flexibility in this because we will come up with circumstances where people are going to get 90% of what we're expecting them to do and fail on something and therefore be ineligible for the incentive. I think that would be a tragedy, and I think it would really be discouraging and a bad signal to send for the next round of what we're trying to do.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks, Neil. Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
I applaud the notion of flexibility here. I think it's really been a great thing to bring to this. I think it's really important that we set a big vision, these are the things that we think make up a full electronic medical record and the kind of changes we'd like to see. I think we should continue to push with that as a very clear and broad scope and deep vision of where we want to go.

But we need to look I would say even more flexibly at the criteria to say the intent here is not to say you get a gold star. You have a complete electronic medical record or you have completely automated your care processes. The intent here is to move the nation along, and if we look at the very low numbers that were reported a year ago in the article that Dr. Blumenthal was a co-author on, if you look at those numbers, you'd say we're not going to make it. Very few hospitals, very few physicians are going to be able to get the incentives.

I think we need to continue to push for a broad statement but continue to be flexible in the criteria and perhaps even soften some of the things you put here. For example, on CPOE it's not clear to me from your note whether you're going from I want to make sure you've turned it on and I've removed the thresholds to I'm including it with the current thresholds. That typically is an area that organizations have a lot of time getting right, and not getting it right could be a patient safety issue, and we want to encourage them to work at getting it right rather than to say we'll never get that right and blow it off or

we'll figure out some way to do it without really doing it, to look at that in particular as sort of a very key thing to where we all want to be, but to give people many options for getting there. I would suggest for example at the beginning that we say your vendor has to certify that they have it, and we want you to turn it on and start collecting usage statistics, but perhaps for the first stage we're not going to score you on that, only that you're getting statistics so you know to what extent you're actually using it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Try to limit your comments and not repeat as much as previous. I want to have enough time for discussion. Thanks. Adam.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
I'll agree with everyone else that flexibility is probably a good thing, but the one issue that I am mulling over in my head is the second one there, whether or not the patient family engagement should also be a zero with privacy and security. I bring this up because this is really the first time that the patient is being brought to the table here. A lot of the discussions have been about vendors, about providers, and if we allow flexibility that a patient will not get electronic health information, are we missing really the opportunity to engage the patients in this? Are we going to delay it to 2013 where they are really starting to get involved? I would like to maybe consider whether or not that should be a zero unless of course there are serious technical challenges with doing this, but if it's not technical, I would encourage looking that patients should be able to say I want my treatment summary and I want my electronic health information.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Just to reassure you on that point, if you look at the criteria in that one, even if you miss one, they will not be denied access to electronic health information, so just wanted to let you know. Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Yes, thank you. This is Art Davidson. We concur with regard to flexibility. I have received many comments from my public health colleagues around this, so I want to convey the concerns of that group.

There are no mandatory criteria for public health in the table that follows this slide. That's the first thing. The states and local entities are very concerned about the lack of an infrastructure really to respond to the meaningful use criteria and that there needs to be something to address that at some point. The absence of that means that in those jurisdictions where it's not appropriate or not possible, there will be no progress in this area. This is a concern of my public colleagues.

We know that in 2013 as we sketched out the beginning of meaningful use we spoke about bidirectional communication with public health, and if we delay or defer this unidirectional process to public health, we'll only delay further the bi-directionalality. We've seen a lot of progress in this area in the last year with the H1N1 outbreak and what was the need for communicating with providers and communities, so I think that we should appreciate what we've recently experienced. We need to send a message to states and local agencies that they need to get ready for this, and somehow we need to build that infrastructure, but by having the providers and hospitals sort of forget this at this stage, we're not sending that message for those states and local entities to start picking this up.

The last point is while the states and local entities may not be capable of receiving this, I've seen some messages from colleagues that say why don't we let the HIE in the state at least receive some of these messages. At least they would make progress just sending the message to the HIE which would then have to take the responsibility of sending this along to the state or local entity. Another suggestion has been that the CDC might set up a test site, a gold standard where some of these things could be tested

an EHR to that test site to see can you really send immunizations or syndrome and surveillance data or laboratory data to a public health-like agency. Those are some suggestions from the public health community.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. Paul.

Paul Egerman – eScription – CEO
I think the flexibility is fine provided that I understood your assurance correctly. Patients have to have access to their electronic health records, so this flexibility is saying that will not be something that can be deferred. Is that correct?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We'll get to that in options two and three when we get there.

Paul Egerman – eScription – CEO
I didn't understand that answer.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
There are three ways that patients can get electronic health information about them, and even if you eliminated one, you still have the other two, so that's the point. We can come back to that when we discuss either the mandatory or the 311. Right now we're just flexibility or no.

Paul Egerman – eScription – CEO
Okay, well, I guess my answer is yes to flexibility. I agree with what Gayle says. It doesn't include privacy, but I'm also saying it does not include patient access to the electronic health records, flexibility in all the other areas.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay. Judy.

Judy Faulkner – Epic Systems – Founder
I'm for it. I think that we own the creation of this, and we're not perfect, and there's likely to be problems in it that it will give people a way to get around some of the stuff that we actually in retrospect might've said good thing that we have that flexibility in there, number one.

Number two, I think some of those things are going to be a little bit like, I liked it a lot what David said about healthcare as a team, and it's interesting with that team, I've been getting some emails, but there's discussion around here on this, and we do see med students ordering in various places, so that's going to be interesting as that stuff pops up and this has effects that we never knew as a group it would have those effects.

The last just as a comment, I used to know a doctor who said the physician who could be replaced by the electronic medical record should be. I've always thought that that really differentiates. There's a lot to the practice of medicine besides what we'll do here.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Jim.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner

Thanks, Paul. This is Jim Borland. I think this is a classic case of where we could fall into the trap of letting perfect be the enemy of the good. The good in this case is improved health outcomes, so I certainly support the concept of flexibility. I'm looking forward to the discussion of the 31110. My concern would only be (and I'm sure that the subcommittee considered this) that in deferring one criteria in any one of those four categories, we not gut the intent of that category, so I'm sure that will be part of the further discussion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Scott.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Last but not least, I too support the concept of flexibility. I think this proposal is a balance between the two pushing the bar of the …, making them move forward, but yet, providing some flexibility, although I don't think going as far as Gayle would like, but I do think it's a fair middle ground, so I do support the proposal of flexibility.

Paul Egerman – eScription – CEO
Thanks. Jodi, ….

Jodi Daniel – ONC – Director Office of Policy & Research
Latanya is on the phone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
On the phone, please.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes, I don't know how to raise my hand. My hand is raised, but you can't see it. I think flexibility is a great addition, and many complements go to that. One of my biggest concern is, though, when the first results come in, we'll want to say to the country what are the benefits realized for these funds. What can we say about our national performance? I like flexibility. I concur that patient empowerment should probably not be one deferred. … what to say in those interviews afterwards what did you accomplish. We don't want to say that patient empowerment took any kind of pass as you wouldn't want to say about privacy.

I also think that Christine's distinction is a really important contrast because if a provider could miss in …, but not know it until they're at the time of the reporting. If they went ahead and deferred something from the beginning and now they come along, now they have an additional one that they're missing, a kind of crisis can set up. Also, if we sort of knew … numbers, even if those numbers are less than threshold, it also gives us a national understanding of the state of the compliance instead of it being a binary. I deferred or I didn't, the threshold is at 80%, but we have quite a few people who came in at 60% or 50%. That would tell us something as well. Also, it also gives us a much better understanding then sort of a deferring meaning a 0% of compliance.

The other advantage to Christine's point is that it demands some attention to all criteria. That is if you have to report it and if a 0% is still an acceptable number, that's fine, but the fact that I have to report would actually make sure that some attention was being given to it, and we don't get pushback in the second year saying it's still too much. Then the last one which I can almost see the payers cringing is the cost … scale reimbursement to match performance.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thanks, anyone else on the phone?

David Lansky – Pacific Business Group on Health – President & CEO
Paul, it's David Lansky.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Hi, David.

David Lansky – Pacific Business Group on Health – President & CEO
Hi. I appreciate the attempt we're making to provide the flexibility, and I do share Deven and Christine's hesitations and concerns about it. I came out ultimately in favor of this approach because I think we are still saying all the elements are eventually required. We're simply allowing a little additional time to achieve them. As I looked at the detail, for example, on the patient engagement category, it did seem to me that the key capabilities that we are concerned about achieving with meaningful use are achieved with even the minus one deferred measure. The category still drives the usage in the right direction in the immediate term, and obviously, we fully achieve the requirements in the later term, so I think that the model we proposed works to push everyone in the right directions in each of the categories.

The other thing I'd add is I also feel the same concern Charles vocalized that we need to give attention to enabling the drug safety capabilities and the efficiency reporting capabilities, but I think we're taken very modest steps along that path in this first round, and they deserve to be certainly supported in the broad recommendations today, but they'll need additional attention as we go forward. Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks, David. Anybody else on the phone? Thank you for passing option one which is that people are supportive of the notion of flexibility. Now, I'm trying to manage how much we're already over time, and in deference to all the other agenda items, I'd like to try to manage the rest of our time on this topic. We won't go into details, but let me expose the 31110 approach to see people's comments. Let's not repeat the same discussion we had. A lot of people spoke in favor, and I think David Lansky summed it up quite well. A lot of it is designed, this whole 31110 program is designed so that it would not obviate people moving in a direction in all five of those categories, but it offers some flexibility, and I think I've addressed some of your concern, Adam, so let's hear people's brief remarks on the 31110 strategy. Marc.

Marc Probst – Intermountain Healthcare – CIO
I can keep it brief. I love the flexibility. I think this is still too aggressive. I think some of the issues on the floor, including CPOE, are going to make this undoable if the feedback I'm getting from folks like the American Hospital Association are realistic statistics, so I love the concept of flex. I think two things need to happen. One, we need to fully define meaningful use over the period of the next five years, and then we need to allow greater flexibility in the sequence on how people get there. I'm very concerned that what we're going to do potentially is take what's currently best practice, what's currently saving lives, what's currently saving money, and we're going to reprioritize it into doing specific tasks that meaningful use have down right now. That would be my quick comment.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. Gayle.

Gayle Harrell – Florida – Former State Legislator
Thank you, and I'd like to echo what Mark just said. I have particular concerns about requiring especially the mandatory objective with the CPOE. I think that becomes very problematic, and if you have certain thresholds you have to meet in that and you miss it by 2% and you're the doctor in the doctor's lounge

who says, well, I did everything and I missed CPOE by 2% and I'm not going to get paid, there's no other doctor in that hospital who's even going to go down this march. I have great, that concerns me greatly. I think we need, here again, even more flexibility. There needs to be some rationale for why we're putting mandatory objectives in there. Perhaps we need to allow a percentage of objectives to be met as opposed to specifics you have to meet other than privacy and security. That is 100%.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other comments? Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I'm just looking at the criteria. It doesn't require 100%, Gayle.

Gayle Harrell – Florida – Former State Legislator
Whatever the percent is, if it's 80% and you come in at 78%. If it's 50% and you come in at 48%, and I defer to the committee to think that through, but I think we need, especially in CPOE, a little bit more flexibility.

Neil Calman – Institute for Family Health – President & Cofounder
Just for clarification, are you recommending that the percentages be reduced or that there be no bar to which people are held because there's a percentage. Are you recommending that the percentage be reduced or that there not be a percentage and people should just, if they achieve 3%, that's cool, and if they achieve 5%, that's okay. I don't understand what your recommendation is.

Gayle Harrell – Florida – Former State Legislator
Excuse me. I think what we need to do is allow the provider to determine whether or not if they want to go for CPOE. Perhaps they choose, but that may be one that they are not quite there, or if they come close, they report what they come to, but that there be some flexibility in whether that is a core measure. You may select the core measures that you want to go for.

Neil Calman – Institute for Family Health – President & Cofounder
I would just speak to the other side of that. I think CPOE's probably the most critical, one of the most critical ways in which we're going to improve quality and safety because it's the use of the systems to be able to provide decision support at the time that people are actually engaging in entering orders that's so critical, and to just remove that as a requirement I think would be a mistake.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Are the folks who are not speaking up yet generally in favor of the 31110? I'm seeing head nods for those on the phone, so it would be appropriate to take a vote on that. Right now we're just voting on the flexibility side, the deferment side using the 31110 approach.

Neil Calman – Institute for Family Health – President & Cofounder
Not on which objectives are mandatory?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Not on mandatory.

Christine Bechtel – National Partnership for Women & Families – VP
But on the presence of mandatory which is you can defer three in the first category, but you cannot defer more than three in the first category.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Correct.

M
If I could just get clarity, you mentioned there were three avenues for patients to get this information. If you could just describe that a little bit because, again, one of my concerns is patient advocacy groups are going to have to talk with patients about this, so that assurance that they will have access is going to be very important.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The three are access to a copy of your record in electronic format. Two is access to information, and three is clinical summaries at transitions, so there are three ways that you can get information, and if you eliminate one of those, then they'd still have to do the other two.

M
Right, and that's where I think I have a little bit of reservation, particularly in the summary end if there are going to be physicians who are saying I don't have to provide that. Is there in a sense risk to the patient as a partner in this relationship there, or is this something that could be a zero?

Christine Bechtel – National Partnership for Women & Families – VP
The thing that I would say is rights to an electronic copy is already guaranteed under the law, so I think it's pretty safe to say that most providers are going to go for that one because they have to do it anyway, right? The difference in meaningful use is that it attaches a 48-hour timely requirement to it. I think it's safe to say that most clinicians will do that, and then that's going to force them to choose between the remaining two which is visit summary. I don't think it's that transition, so I think it's the visit summary and for the patient and then access to their own information. I think you can kind of see which way that's going to go. I share that concern, and if there is broad support for the idea of making this zero, I am all for that. I heard about four or five people note that that was something of interest.

Latanya Sweeney – Laboratory for International Data Privacy – Director
This is Latanya. I would definitely like to see it for zero as well because I think it'll reduce pushback later on in the program.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Are we ready to have a vote, and I'll call that option out as a separate vote. Let me first go with the program 31110, and if you vote for that, we have not yet decided whether engaged patient and family is a one or zero, but I'm calling for a vote for the program of 3 (1 or 0) 110 because it would define an approach at least. Is that clear?

W
Paul, does that include the designated mandatory categories?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
No, right now we're just on the deferral program.

M
Paul, not to lengthen this a long time, but what's the magic of three?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
The magic was approximately 80%. That's how this sort of first came up. Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Just as a suggestion, since Art Davidson also brought up the question on the public health side which I think is important, perhaps we could just vote on each of the sections because we now have two of them that really are in question in terms of what the number should be ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's fair.

W
For having so much time deciding which of our children we're going to sacrifice here, why don't we instead get to a recommendation that asks for lowering the percentages, even though we haven't had time to discuss what those might be so that ultimately what we want to try to achieve is sort of 80% of what we asked for which gets to Christine's point about trying everything, but giving some credit if you fall short of thresholds. We didn't use that approach per se, but I'm just of listening to the feedback here, and it feels as though for folks who want more flexibility and for those of us who are crying about losing some of our priorities here that that might be maybe the better course.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think it's difficult to manage this process and that once we set a number, any number, the same argument will come back, so I think if we can at least start on this approach, it's really approach for option one which is everyone said we want some flexibility, and let's see how far we can make with this approach if that would work. Let me follow, I forgot who suggested now. We'll go category by category, so for category one, the quality, safety, efficiency, reducing health disparities category, allowing up to three deferrals from stage one to stage two. All in favor.

Christine Bechtel – National Partnership for Women & Families – VP
I'm having an issue. You're having an issue, too, but I think we might be having different issues. For me I think it's very difficult to vote on this if I don't know what the bullets are on the bullets are right-hand side because if you tell me that people are not, if it's going to be uber flexibility and they're not going to have to record race, ethnicity, language, and gender data, they're not going to have to e-Prescribe. I think there's not only a problem in the law with that idea, but I'm wondering if there's any consensus around actually taking those categories as part of the vote now with the exception of holding CPOE because it sounds like there's a lot of energy around that and assuming we're adding one on public health.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Let me go back to voting on the strategy, and I'll include what you just said. Another component, as you can tell, we did not achieve consensus in the workgroup in the limited time which included over the holiday weekend. The counter to the pushback we received about the flexibility is to say, well, there are some things that are mandatory, and we want to keep that number small as well.

Let me see whether there's an approach, try to call a vote for the concept of a low number flexibility for deferral or the concept of a low number flexibility for deferral combined with a low number mandatory in each category, so option one—low number flexibility for deferral, option two—low number flexibility deferral plus low number mandatory in each category. Those in favor of option one. There are one, two, three hands for the people on the phone. There are four hands. Option number two, low number deferral, low number mandatory, one, two, okay I think the votes got changed, so it's three in the first one. There's one, two, three, four, five, six, seven, eight, nine, ten, eleven.

W

Of mandatory, you mean lower than what you have here, or do you mean this is low?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is low.

W
This is low?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
This is low.

W
Then I'll move my vote.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It looks like the votes for option two which is a low number of deferrals and low number of mandatory with the majority opinion. Now, let me throw out something for the floor then. The current thing that the workgroup agreed on previously was 31110 for the deferral, the maximum deferral, and then a corresponding (this is new), a corresponding 3111 mandatory, in other words, 31110 maximum deferral, 3111 for mandatory.

W
Wait, what happened to 30110?

W
I agree.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We could be here all day.

M
That's why Congress deferred this to you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That's right. Yes, please.

W
I would like to point out that there are certain things that the statute requires, and I think there are two of them in the mandatory section in number one, so those really, we have no choice over. Therefore, to even discuss them is not germane. They should be taken off the table to start with, e-Prescribing being one of them as well as the demographic information and structure data, quality measures. Those are already in statute, and really, we do not need to be concerned with them.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
May I defer the, and I agree with you, so may I defer the details of what are in those numbers to the workgroup which is meeting again before the letter's going to go out. It's essentially a 311 on the deferral and a 3111 on the mandatory. Is that something that the group would be willing to support?

Latanya Sweeney – Laboratory for International Data Privacy – Director

But what happened to the 30 for engagement patient and family? At first it was going to be an option, too, and then there's no vote?

Christine Bechtel – National Partnership for Women & Families – VP
If we can get consensus on the option—

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Well, I'm testing.

M
…

Christine Bechtel – National Partnership for Women & Families – VP
Well, if there's consensus on the option of what Latanya's suggesting which is 3011, that's the more stringent, then you know there's consensus on 311 probably. It sort of makes sense to start with the more stringent ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, so let's try the line by line. For line one which is the quality, safety, efficiency, reducing health disparities, proposal on the floor would be three and three, three maximum deferral, three mandatory, and the workgroup will figure out which three. By the way, number two doesn't belong there. Basically, it's mandatory anyway. That's just an error on the table.

Christine Bechtel – National Partnership for Women & Families – VP
…

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Correct, and so those three would be probably those three. In other words—

Christine Bechtel – National Partnership for Women & Families – VP
It would effectively taking CPOE out.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
No, so row number one has a maximum of three items that are deferred and three that are mandatory. The three that are mandatory would be CPOE, electronic prescribing, and demographics. Bullet number two is in the table, but that's already mandatory, so essentially, the table would stand. If you vote for row one, it would be as appears on the table. Is there support for that? Okay, let's have a vote. All in favor of row one as on the screen—one, two, three, four, five, six, seven, eight, nine, ten, eleven, so eleven. All opposed—one, two. Okay, so the motion carries.

Row two is engage patients and families, and there was a discussion of whether to have no flexibility in that row versus allowing one. Is that a clear enough decision point? All in favor of having no flexibility—one, two, three, four, five, six, seven, eight nine.

Latanya Sweeney – Laboratory for International Data Privacy – Director
And count me on the phone.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Ten.

M
And me.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Eleven, and those favoring one item of flexibility—one, two, three. Okay, so the no flexibility has that one. The third category is care coordination. The motion on the floor is that there be up to one deferral and a question of whether there's a mandatory.

W
…

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes. Okay, so let's make two options. One is as it appears on the screen which is up to one deferral and that test capacity to exchange is a mandatory, and the other vote would be for not having that mandatory, not choosing which one is mandatory. Option one which is as it appears on your screen, up to one deferral and that mandatory—one, two, three, four, five, okay, five. Then the other option is having the flexibility of deferring one, but not preselecting which is mandatory-- one, two, three, four, five, six, seven. Just barely it's in the one deferral, but no specified mandatory.

Population health is the row that's described as up to one deferred. Let me try that one. Who, yes.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Will there be … as well?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do you want to propose one?

Art Davidson – Public Health Informatics at Denver Public Health – Director
I think the recommendation from the public health community is that there be no deferrals, and there'd be an attempt to make exchange happen at some level. There are lots of qualifications in the way that it's already written—if applicable, if appropriate in this jurisdiction, so those things are already built into the wording.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
That would sound like having no flexibility. The two options are no flexibility and one item deferral.

Christine Bechtel – National Partnership for Women & Families – VP
Before we vote, Paul, clarification, can you remind us of what is in the public health table? I think it casts the ability to send immunization data.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do you want me to read it?

Christine Bechtel – National Partnership for Women & Families – VP
Yes.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Immunization data, it's syndromic surveillance data, and it's public health electronic laboratory reporting.

Christine Bechtel – National Partnership for Women & Families – VP

Those are all one … of each?

Art Davidson – Public Health Informatics at Denver Public Health – Director
Those are three different items, and they pertain to eligible providers and hospitals for two and for the electronic lab reporting, it's just for the hospitals. Does that answer your question? It's supposed to be sending it and be able to—

Christine Bechtel – National Partnership for Women & Families – VP
But there's not a threshold associated with ….

Art Davidson – Public Health Informatics at Denver Public Health – Director
No.

Christine Bechtel – National Partnership for Women & Families – VP
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Those in favor of no option—no deferral, sorry, no flexibility, yes, it's the same thing, no flexibility—one, two, three, four, five, six. Those with flexibility of one deferral max—one, two, three, four, five.

Latanya Sweeney – Laboratory for International Data Privacy – Director
Count me in.

M
I'm flexible.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You're flexible. We have by a narrow margin of one in favor of flexible, so one flexibility for deferral in that category. Privacy and security, I think we all agree there's no flexibility, no deferral. I think we managed to get through that one. Yes, Judy.

Judy Faulkner – Epic Systems – Founder
Just a little bit to the percentages discussion that was earlier, and it may be too complex and maybe it's not workable, but did you consider giving partial credit for people who come very close? In other words, if they're 10%, maybe reduce them 30%. If they're 20%, you reduce them 50%. Then you get over that we came close, we tried hard. I think really the intent in the end is to get people there over a period of time.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think while there's certainly merit in that approach, I don't know that the payers could ….

W
… permit partial payments, so you have to find some threshold for getting the payment.

Judy Faulkner – Epic Systems – Founder
Okay.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Mr. Chair, if I could make a suggestion, you have a lot of recommendations. They're all very thoughtful, but I think you could probably spend the rest of the day on this section. It is very helpful to us certainly have the collective recommendations of this group, but it's also helpful for us to have the individual

recommendations of members of the group, and in the interest of moving onto the rest of the agenda, we might take the collective recommendations of the working groups. If the policy committee wanted to come back again before the comment period is closed and work on this some more, that would certainly be an option. I'm not sure you want to do that, but in lieu of that, we might just invite you all individually to provide your comments to us on the remaining recommendations.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I think we approve the, well, that's a good point.

Deven McGraw – Center for Democracy & Technology – Director
One other option that you have, you can propose a recommendation and note either strong positions to the contrary or other positions in that recommendation letter just to capture some of the points, particularly where there were some close votes. That's perfectly acceptable as well, and we can try to help draft that recommendation letter, bringing in some of the comments if that would make folks feel more comfortable moving on.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good point. I sensed there was, is it fair to ask for a vote on the other 11 recommendations collectively just all as one because I didn't see opposition, so let me test that. For the other recommendations, what is the vote to approve those as part of the letter? As David points out, as always each of us are either encouraged or certainly permitted to write separate letters not representing the group, but we also thought it would be helpful to have a group letter.

M
That's inclusive of the comments that were made today. There was good commentary.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All in favor of supporting the other 11 recommendations including comments, and it passes unanimously. Thank you for your forbearance in terms of recommendation 12, and I think it was actually an interesting discussion, obviously, and it was very helpful to have David and Tony in the room to participate in that, or at least to listen to it.

Tony Trenkle – CMS – Director of OESS
We're listening.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You're listening, right. Wonderful, now, in terms of making up time, we're a half hour behind schedule. Could we shave 15 minutes off of lunch, so bring lunch from 12:00-12:30, and then I'll work on distributing the rest of the 15 minutes through the other presentations? Okay, appreciate it, and we'll adjourn until 12:30.

If we could start gathering together.

Judy Sparrow – Office of the National Coordinator – Executive Director
Operator, could you open the lines for the public? We're ready to resume.

Operator
The lines are open.

W

The lines are open, Judy. You may start.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
In order to try to make up some time, we'll get started. I'm sure David has gotten caught up in something temporarily. He's seen the slides, and then I'm sure he'll want to be part of the discussion, so if we could go ahead and get started with Marc Probst and Paul Egerman talking about the adoption certification workgroup's comments on the NPRM and the IFR specifically. Thanks.

Marc Probst – Intermountain Healthcare – CIO
Great, thank you. It's good to be here. We'll try to make up some of the time, Paul, and I know we're a little behind schedule. It's interesting as we've gone through this process and each step of the process how a realization or a reaffirmation comes up of what we're going through. There are thousands of people starting at different points along the way, and it becomes a pretty daunting task for us. I was thinking that even if we could select one HIT, one EMR, one physician office system for everyone across the system, I'm not sure we could have that implemented by the year of 2012, and so when you take meaningful use and what we're trying to do with all the variables that are out there, I think we have even a bigger challenge. It isn't just about the technology, it's about the workflow, and we're going to talk a little bit about some of the workflow issues that we surfaced through some of the discussions that we had and how it impacts that NPR and the IFR.

We received 16 administrative burden metrics. I thought there was a different set of slides here, but this set of slides will work. The following two pages have those two pages of administrative burdens. What this really had to do with, one of the members of our workgroup was looking at the NPRM and what it meant and basically was saying if all these things stay the way they are, I'm not going there. I'm not going to do meaningful use.

It primarily was around three activities. One is there was data within the EMR, but that data wasn't usable to create some of the metrics that we were asking for, and therefore, to do it, it would require either reprogramming of the system or a new version of the system to get there to actually determine what some of the percentages were, and you can see some of these things that are up there. CPOE usage percentage, well, indeed in this case, it isn't necessarily what is in the EMR. It's what's not in the EMR and how would you determine what you didn't do using CPOE versus what you did do using CPOE and how would you define and create that metric and be able to be accurate in that metric?

Many of them, the data was in the system. The percentage of all unique patients with an active allergy list, that would be all in the system other than the fact that there wasn't a coded field for that, and therefore, to create the numerator and denominator didn't exist in the system. This particular individual felt that would be too much work to go through and try to determine on paper what was happening or external to the system and try and determine what some of these statistics are. I won't go through every one of these due to time.

These are the other eight burdens that were out there. Interestingly enough, I went to Intermountain Healthcare where I work and went to our quality review department and gave them the meaningful use NPRM and suggested to them what do we have to do? How difficult of a burden would this be? Although it would be a very significant burden to create all these statistics, they determined there were 15 functions that would be required in an electronic medical record that were not in stage one meaningful use requirements, so they'd need to be in the system to create the statistics that were looking for. There were some fairly large discrepancies between what we're collecting and what we're asking for, so what the system can do and what we're asking for relative to metrics.

There were a couple of themes, and those themes were specifically, the doctors want to be able to provide the statistics back. They want to be able to prove the use of the system and prove it statistically as we've asked for, but they're very concerned about the manual efforts or the efforts external to the system that would be required to provide those metrics. Again, in this particular example, this physician said if these stay in the way they're written right now, I'm not even going to try, so that's where we came down with these 16 metrics. Now, we didn't just have problems here. We actually have some recommendations, so Paul's going to take us through a series of recommendations relating to the NPRM and the IFR.

Paul Egerman – eScription – CEO

Thanks a lot, Marc. This is Paul Egerman. On these 16 metrics, these are the metrics for the eligible providers, and what we're commenting on is we're not commenting on the value of each of these metrics. We're simply commenting on the process of answering the question. That was the issue that we addressed.

The three recommendations, the first one relates to those metrics, those measurements where you have to look at the percentage of electronic usage versus manual usage, like what percentage of CPOE is done. It's actually a fascinating issue because we are talking about self-attestation, but at the same time, people want to make sure that they get it right, and they want to understand if they're finding some self-attestation document what they're supposed to do. What we are recommending is that we see some description either in the NPRM or in terms of guidance from CMS on every one of these items to tell how the item is supposed to be calculated.

For example, the first question is are rough estimates acceptable? In other words, can a physician sort of say CPOE 80%, yes, that's right and sign it? Is that an acceptable response? The second question is, is a manual review and counting of documents expected? In other words, are they supposed to actually go through and carefully count everything? If so, over what time period?

Another question is can they use a statistical process to respond? In other words, can they simply say, well, we're going to look at everything that happened over the last week or maybe a hospital does a terminal digit thing. All the patient's whose medical record number ends with 05, and they do an analysis of that and then extrapolate that. Question is, is that acceptable? Again, all we're asking for here is guidance or direction from CMS as to how these are supposed to be answered.

The second recommendation relates to those metrics that can actually be automatically calculated. For example, one of the metrics is what percentage of the patients over the age of 13 have smoking status recorded, and so a computer could calculate that for the physician. If the computer can calculate it, the second recommendation is very simple. There ought to be some certification criteria for something called reporting metrics where basically the computer system would produce the report and tell them what percentage met those criteria. We think that that kind of report actually would be very useful from an adoption standpoint, too. A physician would get a report every month or something that says you're at 70%. The metric is 80% for something, and so that might help bring the level up.

The third recommendation is very simple is when we get to stage two, we're simply recommending that you think through in advance the reporting process for stage two, and stage two for meaningful use should not require manual review of records or even subjective judgments. We're recommending that when we get to stage two, the metrics automatically generated by the EHR and be more objective because I think that this creates a difficult situation. Those are our comments on the NPRM.

I also, exactly as you said, Paul, want to speak very briefly about the IFR. In looking at the IFR, what we did as a workgroup is we first looked at our original recommendations to you all back in August and said, well, we see them in the IFR. What happened here? We were very actually pleased with what we saw, so to very briefly and quickly step you through these, we had originally said that the certification process should focus on meaningful use, and that's indeed what we saw. There was not a lot of extraneous functionality. You did exactly that.

The second thing we said was leverage certification process to improve progress on security, privacy, and interoperability. We certainly saw that. In fact, the IFR actually quote the presentation which we were both surprised and pleased to see, but did great. Really did have an entire focus on security and privacy, on interoperability. It specified LOINC and RxNorm, two vocabularies. We were pleased to see that.

The third recommendation had to do with the certification process, and that's something that we can't comment on yet because there's yet another NPRM that is due at any moment. There's a great sense of anticipation about that NPRM, a lot of anxiety because people don't know yet what's going to be in it, and actually, the longer we wait, the greater the excitement and anticipation is, and I'm going to comment on that in a minute.

The fourth one is the expand certification to include a range of software sources, and one of the things we saw very clearly in the IFR was basically all the presentations on modular systems, so that was terrific, and the fifth thing is the transition plan, and I'm going to talk about that at the end.

Those were our recommendations, and this slide basically summarizes what I just said, that we were pleased with many of the responses, pleased with a lot of the things we saw in the IFR. The reason why I'm saying this is what we were asked to do is we were asked to make comments, not necessarily criticisms, and so part of our comment is that ONC really did a very good job with the IFR. It's a complicated task. There's a lot of complexity there. There's a lot of detail there, a lot of very difficult issues, and it represents an impressive amount of work, and so we figured it's helpful to not only point out things that need to be improved, but also helpful to point out things where people did good work, and there was some very good work there.

However, we have noticed that ONC does seem to be accepting our recommendations, and so we felt that we had a responsibility to help create a more perfect IFR. What we decided to do is we do have some recommendations that will help make that happen.

First one relates to interoperability, and there's actually a specific sentence in the IFR that we have some comments about, and this relates to this concept of something called implementation specifications. I guess first I should explain what an implementation specification is because it sounds like something that's dreadfully boring, which it actually is dreadfully boring. What it is, is it's basically very detailed instructions as to how you're supposed to do what a standard says, if it tells you how to meet the standard in a very detailed way. This is a lot of detail, and so you have a concept of certification criteria. You have a concept of standards. Then you have a concept of implementation specifications. Implementation specification is where the detail is.

The next question is, well, why is this important? The reason why it's important is in the absence of implementation specifications, people can look at the standards, and they can sort of, vendors can sort of form their own conclusions as to how they're supposed to do things. They can put leading zeros or spaces. They can form their own conclusions as to how the standard is supposed to be applied, and they can even, the worst part is if they extend the standard for some reason.

The issue when that happens is it's one of the reasons why it happens that we have so much trouble with interoperability because we actually have plenty of standards, but it's an issue of how the standards are actually applied. Another way of saying it is sometimes people say there's too much wiggle room in these standards. Implementation specifications help address this. There was actually a comment made in a blog that John Halamka did last week that I thought was great where he described how things work right now, and he said that the way we're doing interoperability right now, our method of communication is an approach they call the Tower of Babel approach, and that's basically what's happening. Things aren't talking to each other, so these implementation specifications are really important.

The issue, though, is very few of them were included in the IFR. We would like to see more. There was an explanation written in the IFR, and this is the sentence at the end. It says, "We will consider adopting implementation specifications, though, for any or all adopted standards provided that there is convincing evidence submitted in public comment of the specification's maturity and widespread use."

I guess what we are doing is we're actually challenging that criteria because first I want to look at the concept of widespread usage. If we really had widespread usage of a laboratory implementation specification, if everybody was using it, then we actually wouldn't need the government to do anything because we'd already be using it. One observation we have is this when there isn't widespread usage of something may be the exact situation where it's very important that there be some action on ONC.

The issue of maturity is also an important issue, and maturity is sort of a relative thing, but there was a very good point on the issue of maturity. We talked to a number of people as to why this approach … IFR, and there was a concern. The concern was if we implement an implementation standard that's relatively new and you put it in the regulations, the regulations are a big deal. We can see it's not that easy once you put something in regulation to change it, and if these things need to evolve, maybe that's a mistake to put an implementation standard in the regulation, but we think that there's a way to address that issue. The way you address that issue is you simply establish a minimum level and let subsequent revisions also be a part of the regulation.

We basically challenged this concept, and we have as our recommendations are, number one, we think government and ONC needs to provide leadership in critical areas where use of mature standards may not exist, so rather than argue whether or not a standard is mature is simply to say is the area really critical. If it's really critical regardless of whether or not the level of maturity, that's where it's important, and the example we give is laboratory. Laboratory there is a critical need, and whether or not the standards or the implementation specification are mature, we think the government should do something because otherwise we're just going to perpetuate the process we have right now.

The second bullet is relating to the evolving implementation specifications which incidentally also are sometimes call implementation guides. I said they should be designated with a plus sign. Actually, somebody told me the correct regulatory sign is actually a percentage sign, but to indicate that subsequent revisions also meet regulations. The basic concept there is while all these things may be evolving, what we would really do is simply establish a floor, a minimum level. We think that that would be very healthy.

It's a process of actually describing the IFR for standards, but if you do that for implementation specification, you establish a floor. You say subsequent revisions also meet the regulations, but it means when we get to stage two we can raise the bar. If we do that approach, I'm not claiming that that will achieve interoperability for laboratory, but it'll be a huge step forward. It would be a significant step forward in an area where we need to place a step forward.

Then you see there the third bullet a comment about information exchange workgroup's recommendations on laboratory exchange. This workgroup, the certification adoption workgroup has the identical recommendations on lab that exchange workgroup are going to be presenting in a few minutes, and so we're not going to repeat that except to say that we agree with those. Those are our comments about implementation specifications and also the comments about the process that should be used to choose which ones should be included in the IFR.

We have one other area that I wanted to comment on which is sort of similar. It's related to the specificity of the standards. If you look at the bottom part of this screen, you see four areas. In each of these four areas, actually, two or more standards are specified in the IFR. You might look at this and say, now, you guys are really tough. The one place you're complaining that you're not getting anything, and now you're complaining when you get too many of them.

Basically the issue here is that if there are more than one standard specified, potentially, that creates a sense of ambiguity for a developer. They need to understand why there's more then one. At first we thought we're going to ask for more than one which is what you see as our initial recommendation, but then what happened is I started asking around as to why more than one was specified. What I came to learn is that what's written here and is written in the IFR is it looks to me, at least me personally, that ONC probably got it right. In other words, there are good reasons why more than one should be specified for all of these and good reasons right now.

The more important recommendation, at least right now for these four, is what's written there in the middle is … request ONC to explain why more than one standard was specified. The explanation could be in the form of guidance or some text or something. There was actually a very nice description of CCD versus CCR in the IFR, and that's what we're looking for, a few sentences or a paragraph because in the absence of that, there's a concern that vendors will read this and might come to the wrong conclusion in terms of what they're doing because people are looking at this very carefully.

I also want to talk about this other issue, the transition to the other NPRM, but I think the best bet right now might be to pause and see if people have any comments about what we said so far about the three recommendations for NPRM or these recommendations on this specificity for the interoperability.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Comments, questions? Christine.

Christine Bechtel – National Partnership for Women & Families – VP
Just to clarify, I think my sandwich …. In the beginning your first two slides, do they relate to your recommendations or no?

Paul Egerman – eScription – CEO
Yes, you mean the first two slides with 16 items. We were just trying to give you a sense of what these items look like. In other words, you look at the first two slides, and you see these things like CPOE usage percentage, percentage of unique patients with electronic up-to-date problem lists. Question is, well, how do you answer that question? In other words, how do you know what percentage of your patients have an up-to-date electronic problem list?

Christine Bechtel – National Partnership for Women & Families – VP
Okay, so that's your first recommendation is to clarify—

Paul Egerman – eScription – CEO

Is to clarify how you're going to answer that question. In other words, we're not trying to just say whether that's a good thing to measure. We're just saying, number three is actually a good one because I don't see how else you could do it other than a physician saying, yes, I do it. This is my percentage. We're looking for clarification on each one as to what is expected as to how to do that. Other questions, comments? Deven.

Deven McGraw – Center for Democracy & Technology – Director
The conversations about how specific to be on standards where you're sort of hitting that sweet spot where you get interoperability versus what some people have concerns about where it's too regimented and it tends to block innovation in some space. I know that I am in agreement with the ones that you pointed out. I think I'm inclined to be more accepting of the alternative of where as ONC considers each opportunity where in terms of the specificity that there be some explanation where if they're not going to pick one, what's the reason for doing so because in fact, as you pointed out with the CCD/CCR example, there may be legitimate reasons for leaving it a little bit more open, but I think it's good definitely on all the other points you raise, especially on lab.

Paul Egerman – eScription – CEO
Right, and also to be clear, the request for the clarification is when they pick more then one.

Deven McGraw – Center for Democracy & Technology – Director
Right.

Paul Egerman – eScription – CEO
Basically, we're saying that where there's a critical need like laboratory they should pick one. Okay, I want to talk about the transition. If there are no other comments, what we're going to do with this information is we're going to put it in the form of one of these fancy letters. I guess it'll be a letter from our workgroup. We won't make you vote on every row and column. We'll skip that part.

I wanted to go to this issue of the transition. There it is, the transition plan. Again, if you remember the five recommendations that we made, one of the recommendations was for a new open and transparent certification process. That process is not yet, the NPRM for that has not yet been announced. Like everything else, I have no idea when it might come out. It might be any day now. That's what I'm hoping for, but I don't know.

There's some anticipation and some anxiety because it hasn't been announced yet. I do have some sense of confidence that since ONC seems to be influenced at least by all of our recommendations that they would probably be influenced by our recommendations on this certification process, and so I'm taking a guess that what's going to come out is going to be in some way close to the recommendations that we originally made, but then this issue is that the absence of this creates a problem as it relates to a transition plan. What people are saying is, well, the certification process hasn't been announced yet. If it's announced soon by the time it gets published in the federal register that would like March. Then you'd have 60 days of comments, and that takes you out to May. Then something else happens and something else happens you're probably at the end of 2010 before you actually have something in place, and so that's creating some anxiety in the marketplace among both purchasers and vendors who are saying, well, what are we supposed to do until then? How do we know if we're going to get certified, and what are we supposed to be doing?

People seem to be looking at every word that everybody says, and so there was some interview with David Blumenthal where somebody asked him some question about CCHIT, and he said something like, "I don't know what CCHIT's role is going to be," or "I can't say anything about that." Then people got even more upset because they said, well, what does that mean?

We did make a recommendation for a transition plan. The recommendation we made back in August was to sort of grandparent in the CCHIT certifications to admit all the IFR regulations, and I just spent some time talking to Jodi Daniel on the telephone to try to understand the regulatory environment. When I got

all done talking to her, what I basically came away with the conclusion of is that of course I appreciated her time and her efforts to explain to me, but this is an unbelievably complicated area. You look at like taxes and IRS and FCC and Energy Trust, that's nothing compared to this thing. This is like extraordinary in terms of the complexity of it, and the sense I had, and it's just really an impression I had is that the reason that the ONC wasn't acting on our recommendation was that they had run into some legal obstacle to doing that.

The sense I had, and again, it's just an impression, but the reason that David Blumenthal isn't making any statements is probably his hands are tied. I make this comment about how complex the administrative law stuff is, but it does have an honorable goal. The goal is trying to make sure that things are done fairly for all vendors, that nobody gets an unfair advantage. The intentions are really good, but it's part of what makes it happen that you have to have these very neutral statements. In the absence of information, there's a lot of anxiety.

I understand where that is. We still have a recommendation for …, but what is happening also is some of my friends in the vendor community have been asking me what to do, and so I'll just tell you and say to anybody who's listening what I've been telling to vendors on this whole thing. The first comment I make which is a comment that I make for both vendors and purchasers is, well, the IFR is the law. In the IFR it tells you exactly what these systems have to do, and so vendors should be doing what it says in the IFR. It's just a very simple thing. You've got to program your system so it does what it says in the IFR. As long as purchasers purchase the things that do what it says in the IFR, then they're really going to be okay.

As it relates to vendors and wondering whether or not they should keep going through it with CCHIT, the way I look at that is what I've advised to people. I say we have two choices here, one choice which is do nothing and wait until the end of the year and see how it all pans out and wait until every "i" is dotted and every "t" is crossed, or go with the IFR, go with the testing process. You may find yourself at the end of the year in a situation where there's something else you have to do, and that might be sort of really annoying, but there might be something else you have to do to be formally certified, but then you'll be done, and that's better than doing nothing because your competitors will probably have all done that process, and they'll be out in the marketplace, and you won't be.

That's the advice I've been giving to the vendors. What I say to purchasers is what I said before. The IFR is law, and the certification process will be a very good process, but it shouldn't stop them from buying systems right now. The vendors should be able to say whether or not they meet what's in the IFR. Those are my comments about the transition plan, and we have one other slide. Do you want to do the last slide?

Marc Probst – Intermountain Healthcare – CIO
Sure, and we do need to get going so we can get Paul's schedule back on time. We're just letting you know that on the 25th, so about a week, we were asked by ONC to take a look at patient safety issues, or it's basically HIT safety issues and some of the patient safety issues associated with that. You can see the topics on the board identifying the issues, stakeholders, possible approaches. I think we have a very good hearing set up. I really appreciate ONC setting that up. They've done a good job. I don't know how much of this came out of Senator Grassley's letter that was sent out, and I think the responses were due back yesterday. Those responses should be back to the Senator, but I think there are a lot of issues now floating around relative to HIT. We're really glad to be the workgroup that's responsible for that and look forward to the hearing on the 25th. That's it, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great. Further comments, questions? Charles.

Charles Kennedy – WellPoint – VP for Health IT
Just a couple of thoughts, one is in creating a transition plan, I wondered if you'd thought about trying to leverage any of the intermediaries or even health plans potentially for a couple of these eligible provider measures such as eligibility status and claim status. We might be able to be helpful on that one. Then

the second comment is any thoughts around leveraging some of the existing processes that go out and get data from physician offices such as the HEDIS data collection process where we go out and sample information. Any value there as an intermediate step?

Paul Egerman – eScription – CEO
Great question, Charles. That was actually, when we send the letter, it was one of the things we're going to ask is it is allowed to have what we call other sources for the information. Just as you said, one of the metrics is what percentage of the claim forms are submitted electronically? Is it allowed for a physician to ask the carrier, well, what percentage did I submit to you? Another one has to do with medications. If the physician said e-Prescribing … can I just walk across the street and ask the pharmacist what percentage of my stuff is coming across electronically? I think that's a very reasonable thing, and what we hope is that CMS will give guidance that says, yes, that that's permitted because that's what we're trying to do.

Charles Kennedy – WellPoint – VP for Health IT
Great, thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other questions or comments? Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research
I just wanted to make one statement in response to Paul's comments about transition plans since David isn't here. I think you accurately said the interim final rule is final. Obviously, we're taking comment and something can change in there, but it is the final rule, and so I think that that's important. The other thing I just wanted to mention is that over the past two months ONC has been working with NIST to develop some test tools for the certification criteria, and what we're hoping to do is make an early version of that available which maybe faster than our regulatory process so that we can get feedback on them and the vendors can look to those to have a sense of whether or not they're going to eventually meet the requirements and become certified once we have a certification process in place. We are trying to get that moving as quickly as possible and get something released so folks have a little bit more information.

Paul Egerman – eScription – CEO
Terrific. Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle.

Gayle Harrell – Florida – Former State Legislator
Yes, I want to make a comment kind of in general. When I look at the administrative burden of those EP metrics that are going to be required in order to prove meaningful use, I have a great deal of concern. It goes to the whole issue we had a big discussion on this morning. If we are going to encourage doctors, hospitals, physicians to adopt electronic health records, I look at this list and it's overwhelming to me, and I'm thinking if we don't make this easy, if they have to go out and get those measures, get those figures, or calculate them by hand and put someone in their office in order to do it, we're defeating our whole purpose. We're making it even more difficult on those providers, and we're making it less likely that they're going to adopt, so as we determine how this is going to happen, we need to make sure that that record through the certification process does this within the record and does it electronically without having to put any burden whatsoever in addition on that provider. That, perhaps, is something that should be addressed through the certification process that the record itself calculates whatever the measures are, and it doesn't cost an additional amount of effort, work, staff, or whatever to do it.

Paul Egerman – eScription – CEO
Yes, that's exactly what we recommended.

Marc Probst – Intermountain Healthcare – CIO
Yes, that's consistent.

Paul Egerman – eScription – CEO
That's exactly what we recommended.

Marc Probst – Intermountain Healthcare – CIO
We would agree.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do you think we can get there in 2011?

Paul Egerman – eScription – CEO
Absolutely. Actually, the reason I say that with such confidence is to calculate 10 or 15 things by hand may seem like an incredible burden, but to write a program and run through the database and come up with the 10 or 15 measurements is not that big a deal. It just really isn't and certainly in my mind a reasonable reallocation of effort. People say all this money is going to the physicians. Well the physician's only really get visiting rights for the money. The money really goes to the vendor or a good chunk of it, so it's not unreasonable to have them write this one program to give these answers. It's not a big deal.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I'll just offer another view that it's a little more challenging than that.

Paul Egerman – eScription – CEO
I don't think so.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Your partner might say so, too. Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
To sort of clarify that, it's easy to count if the other issues we raise get addressed. If it's clear what it is that needs to be counted, if the thing to be counted is actually coded, if it's something that exists inside the computer system and its ability to count and not something that's trying to ask Intuit how many manual orders somebody wrote.

Marc Probst – Intermountain Healthcare – CIO
I think the problems can be solved by 2011, but not necessarily everything programmatically. I think maybe that's what you were saying as well, Larry.

Paul Egerman – eScription – CEO
Well, yes.

Marc Probst – Intermountain Healthcare – CIO
Some of the other decisions need to be made that we recommended.

Paul Egerman – eScription – CEO
Yes, I didn't mean to suggest that everything could be done programmatically, because some of the metrics simply can't be done that way. Also, you're exactly right, Larry. There needs to be some clarity on some of these things because otherwise it's hard to know what the right time periods are, and you can't write the program until you know the answer to that, but we need to know that answer anyway. The sooner we get all that, it is very reasonable to get the program put together.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any final comments or questions? Gayle.

Gayle Harrell – Florida – Former State Legislator

The second point I did want to make is also on the process. Here again I have a great deal of concern on timeframes and the aggressive nature of everything. If the certification process is not in place until 2011, yes, your vendors will be starting to construct built on what's out there on the IFR, but you also have to, to prove meaningful use, you have to have that certified product. Again, the timeframe presents great difficulty out there, not just to the vendors, but to the purchasers as well. The whole thing makes me extremely nervous as we move forward into this. The quicker that happens to ONC, to the regulatory process, I think the better for everyone involved, and I would certainly encourage the movement of that in making it happen as rapidly as possible and perhaps in giving, again, more flexibility within the process for the people who are actually going to have to implement this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. All right, thank you very much, and thanks for the time back. The next group is going to be the information exchange workgroup, Deven and Micky.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Afternoon, I'm Micky Tripathi, and I'm the co-chair of the workgroup with Deven McGraw. It is our aim to give you a lot of time back. Now, if the committee decides to badger and harangue us, then there's nothing we can do about it, but we have every intention of giving you a lot of time back.

All kidding aside, Paul and Mark, I think, nicely teed up some of the issues that we're going to talk about anyway, so I think we can move pretty quickly through our recommendations. Also, these are issues that we talked about in our workgroup recommendations back in December. I don't think that there are any new issues here on the table that the committee hasn't talked about it before. Obviously, we didn't have the benefit of having NPRM and the IFR at the time to speak specifically to, but I don't think you're going to see any new issues here, so that's a little bit of background as well.

I'll quickly go through a little bit of background and our recommendations, and the floor is always open to Deven to make a clarifying or correcting comments along the way as I speak. The first point on background is just what's the problem that we're trying to solve? What's the problem that we see here? In general I would say and one thing I noticed in this first bullet is that we don't specifically say in the bullet because our heads are so deep in it that we're speaking to labs when we say this. That first paragraph actually doesn't say that, so you might come away thinking that we're talking about structured data generally. We're speaking to laboratory results in particular.

The problem as we see it is that eligible professionals in the IFR and the NPRM, or the NPRM in terms of their use, are required to incorporate a significant amount of structured data, but the IFR and the NPRM essentially don't make it any easier than the world they live in today to be able to accomplish that, and that strikes us as being not only just a missed opportunity, but almost one of the preconditions we would say to having sort of meaningful use at the end of the day if we're going to try to move this forward. In particular, there are content exchange standards for EHR systems to receive structured data which seemed like a glaring omission from our perspective.

Also, we talked about this in December that hospitals deliver the majority of labs across the country. A current estimate is something like 75% of labs delivered by hospitals and local labs. This is not a Quest and LabCorp thing at the end of the day. It's really about a very fragmented market for delivery, but given that hospitals in particular are meaningful use incentive payment recipients, the NPRM and the IFR does not impose any requirements on hospitals to send structured data to eligible professionals and doesn't talk about any standards if they do, so that also struck us as being an omission. On the one hand, we're saying that eligible professionals are required to have structured data and even have systems to receive them in some way, but we're not saying anything about the sources of that data sending it according to those same standards, so that struck us as being an open question that needed to be answered.

We also point out that even where standards are specified, they're somewhat ambiguous and don't provide the amount of clarity needed to motivate vendor innovation and development on this front. You could certainly make an argument that any kind of restrictions or guidelines hamper vendor innovation, but I think as we kind of talked to a number of different vendors, almost every vendor I've talked has

talked about these areas, and indeed, we have vendors on the IE workgroup that setting certain guardrails in certain areas is actually a boon to innovation because it sets up the guardrails and allows them then to innovate within those guardrails. Right now without any direction whatsoever, it's actually more paralyzing than anything else.

In terms of the implications, why we care about this, well, one, I think, implication is that without significant strengthening of the lab portions of the NPRM and the IFR, we may need to consider weakening other NPRM stage one objectives because they are founded on the assumption that there will be robust structured lab data to enable those. That would be one consequence that if we don't do anything more in this area that I think as a committee we may want to then say that we need to circle back and say, well, do any of these other things make sense if we're not going to move further on structured lab data.

Finally, we would just note that the federal government has a wide variety of levers that it can use to reinforce the NPRM and the IFR, so not just meaningful use incentives, but CLIA, other kind of levers through state HIT coordinators that we would encourage to be thinking about and be cognizant of as they go forward here. Anything I missed?

On these two slides, this is just a slide that shows what the requirements are that are in there in the NPRM and the IFR. I won't go into any of the details unless anyone's interested, but it's just verbatim just as a point of reference, and here are just a few of the, at least the main other objectives that we think would be affected by not having more robust requirements around structured labs in particular, everything from decision support to being able to generate registry types of lists of patients who have this or that condition and also quality measures importantly. A large number, I haven't counted up, but a very large fraction of the quality measures that we're talking about have either embedded explicitly or implicitly having lab data that you can use to identify patients or identify the condition of the measures focused on. Again, if we don't have structured lab data in a more solid way than we have now, a lot of those would be highly questionable in terms of their implementability.

Let me just move right to the recommendations then. For stage one our recommendation is first off the adoption of the HL7 2.5.1 implementation guide which specifies HL7 2.5.1 and LOINC specifications. The implementation guide would be the basis for the definition of structured data. If you go back to what the NPRM says, it says that eligible professionals have to have 50% of their labs as structured data, but it doesn't define what structured data is. What we're recommending is that this be the definition of structured data, and it's very much in line with what Paul and Marc were talking about from the previous workgroup about having an implementation guide or specification, not just stating the standard.

Deven McGraw – Center for Democracy & Technology – Director
Just to be clear, that 50% is when received from the lab as structured data which makes this next set of recommendations even more important.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Thank you. The second recommendation which would follow from the first is extending the same HL7 2.5.1 certification criteria for hospital lab reporting that is in there today for public health, but extending that to all lab result reporting, as it says parenthetically, not just the public health reporting as currently specified. The IFR says that there is a standard for content exchange. That's the standard that hospitals are required to abide by, but just for public health reporting and is silent on ambulatory reporting which seems to us to be kind of a mystery as to why we would just talk about public health reporting and not talk about an equally important category of results delivery. We would just say let's extend that to apply to all lab results, not just public health.

The third is requiring, this is in NPRM, about how would they demonstrate that. That's essentially extending the model that's already in place for public health reporting, but it would just say require that hospitals demonstrate this capability through at least one test. Again, that would just make it exactly parallel with the requirement for public health reporting, so that way at the end of the day with these two recommendations all we're doing is saying that the standard and the way that you demonstrate your adherence to it or the requirement that you have to meet for stage one is the same for all labs performed

by the hospital, not just narrowly confined to public health reporting which in many ways is kind of an artificial sort of distinction as it's currently written.

The next is to include the 2.5.1 content exchange standard in certification criteria for eligible professional and hospital EHR technology as a certification requirement. Right now it says that there is a vocabulary standard that's currently specified in the IFR, but it says that it has to be able to accept LOINC if LOINC is delivered to the system, whether it's a hospital EHR or to an ambulatory EHR or eligible professional EHR, but it's silent on the content exchange. All we're recommending here is that it specify a content exchange standard as well in the say way.

Finally, this was a point that Marc and Paul raised previously is reducing the options for public health reporting, content exchange, and vocabulary standards, or at a minimal explain the circumstances in which these standards would be required. Right now it says that, for example, HL7 2.3.1 or 2.5.1 could be used for public health surveillance reporting, and there may be very good reasons for doing that and we have every indication that there are good reasons for doing that, but it's not explained, and so it would be very helpful to explain in which scenarios or use cases or circumstances 2.3.1 would apply versus 2.5.1 to give further guidance and to reduce the sense that there are many standards that anyone can use and just pick and choose the one you want.

Those are the phase one lab recommendations. We have one as it relates to e-Prescribing which it really deals with a measurement issue. The recommendation is to refine the e-Prescribing measure to account for markets in which 75% of e-Prescribing may not be possible. Just a step back for a minute, the measure right now for e-Prescribing is that 75% of your eligible prescriptions have to be electronically transmitted. Right now that is essentially the Surescripts network which is the network over which that would happen right now, and there are many geographies in the country where Surescripts' penetration on the pharmacy side would not allow someone to get to 75% even if they were in all good faith trying to do e-Prescribing 100%. It would essentially say that we need to refine that ERx measure to accommodate those scenarios where the physician is genuinely trying, but just isn't able to because of where the technology is right now.

The last one which I'll just take quickly is really for stage two as it relates to labs, and it's really just about a forward-looking perspective of saying that what we want to do even though we're not able to fully specify what stage two is, wanting to be able to send signals, important signals to the market about where that's headed, and in particular for lab ordering which … right now, wanting to be able to signal what the standards are going to be for that so that the market can begin responding to that.

Deven McGraw – Center for Democracy & Technology – Director

I think the only thing that I would add as a point of clarification again is when we talk about what our recommendations are for the IFR, what we're talking about is what the systems must have the capability to do. When we talk about hospitals needing to have the capability of sending labs and using the standards both for public health as well as to their clients who order labs from them, whether that be physicians or other providers, that's about system capability. That should be what they ought to have. Then for meaningful use we're asking for the same measure essentially as Micky pointed out for both the public health reporting as well as for the actual reporting of lab results which is that you perform one test. In other words, so if we've got hospitals that are using different standards, they've got to get that capability in, and then they've got time, they've got to perform one test, so it seemed like an inherently reasonable thing to ask.

The last thing that we'll plug here which is something that we went over in our December meeting, and it was the only piece that we were able to sort of get endorsement from the policy committee on a kind of complicated set of recommendations that we brought to you before which is those with respect to CLIA. We've got some recommendations on the table today that take the hospital lab portion, which is a significant portion of the marketplace, to get them to be using the standards in their reporting of results, but ultimately, you also want to hit the independent labs, and CLIA is the way to do that. In fact, there's some work being done on that, and we just want to, I guess more as a public service announcement than anything else, endorse getting that survey and cert letter out so that the process of getting the

independent labs to be sending using the same structured data can happen and similarly working with state health IT coordinators through the state health IT grant program. The more levers we can use to push this standardization, the faster we'll get to interoperability and the ability to both send results and also order using structured data. I think we're done.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, comments, questions? Yes, Tony.

Tony Trenkle – CMS – Director of OESS
Micky, I understand where you're coming from with the e-Prescribing and the situation in various parts of the country, but do you have any more specific thoughts on how or recommendations for that problem can be better addressed without getting to such an administrative nightmare in terms of looking at different metropolitan areas?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Yes, the only thing that comes to mind is the one that you just ruled out, but—

Tony Trenkle – CMS – Director of OESS
I didn't rule it out. I just said from an administrative—

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
It seems to me that the … does have a tremendous amount of data that I think they could carve up geographically in some way that may not be perfect, but might get the large majority of practitioners might get a more meaningful denominator for them than if we just uniformly applied 75%. It doesn't mean that there wouldn't be issues around the edges of each of those carve-outs or whatever, but I think that they could get us a long way toward what we want at the end of the day. The obvious answer at the end of the day is to have 100% penetration at the pharmacy level, just made up another level that we try to pull.

Deven McGraw – Center for Democracy & Technology – Director
I wonder if there's any way to use the CMS regions in some other way to sort of get a carving of the landscape.

Tony Trenkle – CMS – Director of OESS
We can use the regions, but if the pharmacies aren't ready to receive the data, that doesn't help us much. I think the problem that Micky's pointing out, particularly with the independent pharmacies, there's a lower penetration rate in terms of being able to do e-Prescribing, and I don't know how we're going to get around some of that over the next several ways, but certainly, we're open to recommendations.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Maybe there are just two categories that you could say that anyone in these certain geographies that Surescripts could helps us define are high enough that 75% is reasonable, and then everyone else who's not because know it's relatively thin, we'd essentially have to report what percent they have, but be a little more lenient on the 75%. Again, it's not going to be perfect, but I think there are probably lots of other areas where we do that kind of thing where you make rural/urban distinctions where there are lots of gray and other things like that.

Tony Trenkle – CMS – Director of OESS
Yes, and the other issue gets into who the patient wants their prescription sent to as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Jim.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
I think the answer to that, Tony, is actually in the IFR where it talks about 75% of the possible. Geographic distinctions, yes, they exist, but they're fluid, and they're dynamic, and they're constantly

changing. A prescription that cannot be sent electronically to a pharmacy it is in that case not possible. It changes your denominator, not your numerator. I think that's probably the sensible solution, and I think it's probably just a matter of interpreting the IFR.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Provided you could get that denominator. Paul and then Neil.

Paul Egerman – eScription – CEO
Actually, I have a comment on this issue that was similar. My comment was it seemed to me the e-Prescribing software is if it can't send it to the pharmacy, ought to print it out, and then you should be able to count that also as counting. You tried to use it would be my suggestion.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I guess two points. One is if this gets too complicated, Tony, maybe the answer is to reduce the threshold to a place where we can sort of make it be fairly assured that anybody across the country could meet it because there are other categories. There are those states that don't allow electronic prescription of controlled substances, or maybe that's federal. I don't know, federal, …

W
Yes, but those aren't permissible …

Neil Calman – Institute for Family Health – President & Cofounder
So you have that whole issue. You've got patient preference. You've got the pharmacies now that are basically offering $8 prescriptions for a list of 50, and people are walking out with their paper prescriptions and shopping for the cheapest place to get their prescriptions filled, and we're finding increasing numbers of people that want their prescriptions filled at more than one pharmacy where they have some that go out to mail-order pharmacies, some that they take to their local pharmacy. There are all kinds of combinations and complications, and I think if you try to mess with the denominator here, we're going to end up with problems. I would suggest that maybe we just try to figure out what number is realistic in order to keep this simple and not create a situation where the denominator's so complicated that that becomes harder to measure than the numerator and see if we can't work with that because really what we're trying to do is create a capability here in the first phase and to be able to make sure that everybody has the capability of doing this and has the systems in place that have the capability and sort of moving people in that direction, so just a thought.

Tony Trenkle – CMS – Director of OESS
I was just going to say, it may because there are two parts to this. One is about wanting to encourage 100% of prescriptions through the EHR. You actually do go in and actually do the prescription so you're no longer writing anything on the pad, and then those cases where the patient wants it, great. You print it out and you do that, and then it's either sent electronically or e-Fax. I would point out that related to one of the recommendations around reporting requirements out of an EHR that Paul and Marc had talked about, with the systems that we deployed for the … project, we get real-time reports from the EHRs that we deployed on the prescription activity. It'll say X number were prescribed. X percent of those were printed out. Y percent were faxed. Z percent were sent over the Surescripts network, so maybe that's a way of getting a more refined look at this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Do you have a followup?

Neil Calman – Institute for Family Health – President & Cofounder
Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay.

Neil Calman – Institute for Family Health – President & Cofounder
Again, when you're thinking about that, there are all the real-life situations where even 100% of things going through the system don't happen. There are the people that call you when they're standing at the pharmacy in real life. They don't have any refills, and you're authorizing them over your cell phone. There are all kinds, all of those things will eventually count in the denominator of prescriptions that are filled for which there's no electronic prescriptions necessarily in the system. This is not an easy sort of one path, one workflow kind of process. People get this stuff done in all different ways.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Charles.

Charles Kennedy – WellPoint – VP for Health IT
… does e-Fax count as electronic or no?

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
My reading is that it doesn't.

Neil Calman – Institute for Family Health – President & Cofounder
No, it does not.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
It doesn't say it explicitly, but my reading is that it doesn't.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I would just build on Neil's comment about having just a lower denominator because it's in the practices best interest once you already connect to do as much as you can anyway, and it becomes a hassle for all the other things, so we have ways of doing … where it's not possible, then we do the e-Fax, etc. Once we get the functionality implemented, I think that's what everybody wants it do anyway, so finding some number where we don't have to regionalize the country may be a good approach. Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research
… flexibility?

Tony Trenkle – CMS – Director of OESS
Without getting too much into the flexibility ….

M
… rigid.

Tony Trenkle – CMS – Director of OESS
No, I think the point is where there is part of the infrastructure that varies in different parts of the country and could impact the percentages and even ability to do a type of transaction at all, I think that's something would be helpful if the committee would maybe kind of point out that and look at some of these percentages in that light because that is a big issue with e-Prescribing, and that's also an issue in other areas as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle.

Gayle Harrell – Florida – Former State Legislator

I also want to point out that that is frequently a thing that the provider has no control over. Those decisions are made frequently by patients. The intent is there. The ability is there, but they are not the decision-maker at the end of the road, and the penalty is on the provider.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other comments. Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Yes, I'd like to return to the comment here about extending the HL7 version 2.5.1 certification criteria to all laboratory reports from the hospital. Where certification occurs may make a difference. If it was saying that the hospital needs to send out a 2.5.1 message is one thing, but what happens if the HIE says I'm going to give you a service. You send it to me in 2.3.1, and I'll convert it 2.5.1. Where does the certification occur? Is that good or not? In addition if we said that it needed to be LOINC encoded and someone does a mapping for idiosyncratic codes to LOINC and that is maintained at the HIE, again, the potential exists to achieve your goal, but not necessarily have it certified at the hospital.

Deven McGraw – Center for Democracy & Technology – Director
Paul, go ahead.

Paul Egerman – eScription – CEO
…, Art. The way the certification process works in the example you gave, there is a concept of modular certification. If the HIE does it, that counts. In other words, you can treat that as part of your process, so that would count. I'm going to also tell you the way, at least that's the proposal. We don't know what's going to be in the NPRM, but that's what the proposal was that that would count. Then the other comment you had about LOINC, the implementation specifications tell which LOINC codes have to be met for that because it doesn't really require all LOINC codes to be transmitted.

Art Davidson – Public Health Informatics at Denver Public Health – Director
But the LOINC encoding does not need to occur at the hospital as long as it's modular as well, right?

Paul Egerman – eScription – CEO
…

Art Davidson – Public Health Informatics at Denver Public Health – Director
Okay, great.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Well, let me maybe challenge that response a little. So you must use a certified EHR to do the things that are required by meaningful use. The part that struck me is when you said the HIE could do that. I can understand all the modules of what you might call your EHR set of software, but when you stepped over and said the HIE could do for you and that could count, that goes beyond what I thought.

Deven McGraw – Center for Democracy & Technology – Director
No, you have to be using certified EHR technology which is either your EHR system if you're buying one system, or the modular approach which collectively together which I don't know why that wouldn't include if you're using an HIE to perform some of the functionality that you have to be able to demonstrate that you're doing.

Art Davidson – Public Health Informatics at Denver Public Health – Director
You're essentially making a representation that for certain specific functions, the HIE is performing this on my behalf, and that's how I'm attesting to CMS that I'm getting this done.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
You're saying that an HIE that did clinical decision support would qualify as well?

Deven McGraw – Center for Democracy & Technology – Director
That's I think a question for the certification workgroup which was trying to, I think, create a very broad spectrum of ways that you can meet certification without necessarily having to do it through one system.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Depends on how you define it, certified EHR technology.

Deven McGraw – Center for Democracy & Technology – Director
That's right.

Paul Egerman – eScription – CEO
We have to see what the process is. It might. In that example it's unlikely. I just can't understand how the workflow would work right that would be able to do that. There might be and it's very possible.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Yes, that was going to be my question. How could you contemplate that, and then also, aren't you trying to signal that very soon we're going to be asking people to do electronic ordering through the same sort of pathway. Would that go through the HIE, too?

Deven McGraw – Center for Democracy & Technology – Director
Except we're not requiring anyone to use …. We're just suggesting that if that's a mechanism that they choose through which to do it, then they should be able to get credit for it if they do so.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
It's purely about their choosing to do it in that way because they see that as being the most efficient way to do it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Christine.

Christine Bechtel – National Partnership for Women & Families – VP
Building on this, I think that is a really smart approach, and when I think about the same construct in terms of patient family engagement and looking at other ways that clinicians could reduce the burden that they face by partnering with an external entity to provide consumers with access to their information, I think … a tremendous amount of sense.

Latanya Sweeney – Laboratory for International Data Privacy – Director
This is Latanya. I would just also … a little further. It also introduces another business model for manufacturers to follow sort of the service … model where one entity may not be in HIE, but … outside group can actually take on much of the responsibility, and the modular approach supports that where as the nonmodular approach locks in the computer technology … the provider.

M
I was going to ask a question about the labs, the H1 labs, and you have three bullet points. One is adopt the HL7 2.5.1 implementation guide which includes LOINC as the vocabulary and make that the definition of structured data. I get that. The other is to require hospitals to demonstrate that capacity through one test, so you're not saying that hospitals must actually transmit their data in structured format for stage one. You're saying adopt it, test it, but not necessarily transmit it to the providers you serve.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
That's right. We just wanted to align it with what the public health reporting requirement was right now.

M
That aligns it, but it doesn't necessarily help the recipient qualify except for the denominator which says only your denominators are only those that you receive in structured format.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Right.

M
Now, we could have a bit of a, so the loophole, the perverse loophole is not to send anything structured so that nothing would have to be required.

Deven McGraw – Center for Democracy & Technology – Director
Yes, I think there were probably a number of people on the workgroup who would love to push on that harder, but I think consistent with the approach overall which is the sort of phased in getting to greater degree of exchange using structured data. We didn't want to put any more requirements beyond what they already have to do for public health. I'm going to borrow from Paul Egerman's statement on the cause, basically using the same furniture in a different room.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
I think there's good reason to believe, though, that if you say that you've got to demonstrate the capability for it, it's lined up with your public health reporting requirements, and you have to test it at least once, it's certainly my experience with many, many hospitals is that that will set them up to start doing it because every incentive to start doing it that way. It's not as if they care religiously one way or the other. They want a way to do it and a way to standardize it, so I think that the market incentives will then allow that to sort of proliferate more. I think it also allows a transition so that we're not saying that you have to tear down the things that are working now, so I think that's important. A lot of hospitals have a lot of interfaces up and running, so this isn't saying tear those down. It's saying that as you transition those over time then transition them this way, but keep everything that's working now still working.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any other final comments? One question is whether we should vote on the sense of the committee to allow you to go forward with your letter incorporating these recommendations. Would that be appropriate? You're still in listening mode. Does the committee feel supportive of these recommendations that have been presented so they can move forward with that in their letter? All in favor? Looks like there's no opposed. Thank you very much.

Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO
Great, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
While we're replacing the panel with the next panel, could I ask the same question of the previous presentation which was from the adoption certification workgroup? They had a set of recommendations. There were three up at the beginning. Does the committee feel comfortable in supporting them going forward with those recommendations in their letter? All in favor? Any opposed? Okay, very good. Thank you. Deven is still up there.

Deven McGraw – Center for Democracy & Technology – Director
I am. They gave me the option to move back to my chair until I realized sitting here that it's a little bit like having a teleprompter, and you can't see it from that vantage point.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, and then Rachel's on the phone I believe.

Rachel Block – New York eHealth Collaborative – Executive Director
Yes, I am. Hi, everybody.

Deven McGraw – Center for Democracy & Technology – Director

Great, thank you, Rachel. We in the privacy and security workgroup spent some time also talking about the privacy and security meaningful use criteria and a little bit as well on the certification IFR, and that's really where our recommendations are directed today. Let me start with a little bit of framing here which is, the first one I think speaks for itself, but we'll say it anyway. Really, privacy and security are quite foundational to securing and maintaining trust in health information technology and electronic health information exchange. The meaningful use criteria and the certification standards are tools to promote health IT, and so consequently, we have to have privacy and security provisions that are incorporated into each stage of those criteria to address the risks associated with really what I think will be advancing levels of information sharing, access, and use.

In addition to using those tools that we have at our disposal, we think it's important that our recommendations sometimes address what might be necessary "upgrades," and I put that in quotes because we do have some existing federal privacy and security rules that are in place, but to the extent that those may need some modification to, again, address the enhanced risks of what we're taking on here, we think that that should be on the table. But today's recommendations are largely with respect to meaningful use and certification standards a little bit of a hint where we think we want to go in the future, recognizing that we don't have the opportunity for a whole host of reasons to get maybe our full wish list enacted as part of meaningful use and the certification IFR.

This next slide is really just a reminder of what is in the meaningful use proposed rule that applies to the privacy and security field. There's the objective of protecting electronic health information created or maintained by the certification EHR technology through the implementation of appropriate technical capabilities, and the measure is to conduct or review a security risk analysis per. That's actually the regulatory site to the HIPAA security rule which requires that a risk analysis be performed and the security rule applied to electronic technology and then to implement any security updates as necessary. That's what in the rule today.

We're now going to go through a set of recommendations here. The first several are really directed at strengthening those existing criteria that we just saw, but we also have a couple restore a criteria that were in our original policy committee matrix, but which did not end up in the NPRM. Finally, we have some suggestions, again, with respect to more along the lines of some security policy recommendations and standards that didn't get in in the first round of the certification IFR and for which it might not necessarily be possible to do so during the …, but which we think are important, and those recommendations are a little bit more of a signal for work that we would like to do in followup promptly.

These first set of recommendations, again, are strengthening the criteria, so I think we need to make it clear that for EPs, eligible professionals, and hospitals if they've never conducted a security risk analysis which is going to be true for a number of them because they've not ever adopted electronic technology and that's what this security rule applies to, the requirement is to conduct an analysis, not to review it. They have to conduct the full analysis and that the option to review really ought to be only for those entities who have recently conducted a security risk analysis, so they're using electronic technology, and they're adding new capabilities, and we make that clear in the second piece of this recommendation.

The other thing we have to add here is that, and this should go without saying, but I think it's worth emphasizing to providers to allay any confusion which is that any meaningful use criteria that we put out really not in the privacy and security field, but with respect to sharing of data for care coordination and how data gets used does not and cannot supersede any existing state or federal laws that place some parameters around the access, use, or disclosure of health information. In other words, you cannot use the meaningful use criteria to say, well, I have to do it for this, and so therefore, the legal pieces are not in place. Again, this is something that I think is just helpful clarification since there is often a lot of confusion among providers about what their legal responsibilities are in the field, and now we're throwing some new ones at them, and it doesn't hurt to be clear.

Second set of criteria and this goes back to the security risk assessment. Again, because so many of the eligible professionals and hospitals who are getting these financial incentives this is going to be the first time that they've ever conducted a risk assessment, we think it's very important that they have guidance about how to do one and how to do one well. Ideally, this guidance would be in the form of something coming from the Office of Civil Rights which now enforces this security rule to indicate what they would look for in doing audits which they are required to do of this security rule under the economic stimulus legislation. We're not aware that any of those exist, but it would be helpful to have those because that provides really clear set of directions to entities with obligations under the security rule about what the enforcing authority's expectations are, but we think it's also helpful.

There already does exist actually some materials on CMS's Web site, materials from ONC, materials from OCR and NIST, really ought to be made available through multiple channels, state HIEs, Medicaid offices, CMS regional offices, the regional extension centers, any sort of viable mechanism for getting good guidance out to providers and hospitals about how to appropriately perform one of these risk analyses would be very helpful. The guidance ought to address sort of greater environmental factors as well as risks that are inherent in the technology, and it should also indicate what types of criteria should trigger a review, so you've done your sort of initial assessment, but then down the road you may be adding new criteria. There could be a list of things that are helpful reminders to you. Again, as a provider who's new in this space, if you're adopting this new piece of technology, you ought to review what that means for risks to the security of the data.

We also think ideally any of this guidance on risk mitigation strategies ought to be tied to the security features that are required for EHR product certification. If the guidance that we're sending out to providers actually doesn't speak to the particular functionalities that now have to be in these systems, it's not going to be as helpful, and so notwithstanding that certainly in a sort of little environmental scan we did of materials that were out there, and they looked good, I don't know that any of us looked to see whether they appropriately captured these new technology features that are required to be in the equipment. I think that would be helpful.

This last sub-bullet on here is kind of more of a statement of fact than a recommendation per se because we had a fair amount of discussion of it in the workgroup which is you're not required to bring in an outside party to do your security risk assessment under the HIPAA rule, and we're not suggesting that people be required to do that, but certainly, if you choose to do so, then that ought to count, and it might be helpful for providers to do that, but we're not requiring that.

The second piece of this is not to just provide some clarity on what to do in a risk assessment, but also what do we mean when we say implement security updates as necessary? We had actually a bit of a split in the workgroup between people who automatically thought that this meant, well, this is just the software upgrades that come from the vendor. You just have to implement those, and that's what this meant. I took it mean, well, no. You have to fix what got uncovered in your security risk assessment, and essentially, we decided that ideally, you should have to do both.

More specifically, what we're recommending here is that with respect to software updates that are sent by the vendor, the EPs and the hospitals ought to have a written policy regarding how they're going to handle those updates. It would be even more ideal if the guidance gave them some pointers about how to consider in a way whether or not put those updates in place. I think we went back and forth among those of us in the workgroup with saying they have to do them all and they have to do them all within a certain time period and then realizing that in this space there's a fair amount of flexibility that is due based on the resources of the entity and what they think makes the most sense while still providing adequate security for the data that they're maintaining and exchanging. At a minimum they have to be thoughtful about it which means sitting down and deciding how you're going to handle these software updates.

Again, as I said earlier, responding to the update shouldn't be enough to satisfy this implement security. Instead, EPs and hospitals should also really have to address deficiencies that are identified in the security risk assessment. That response should include what are you going to do with the new security capabilities that are required to be in certified EHR technology.

For the most part, the security policy requirements, the implementation specifications under the HIPAA security rule are addressable. They're not per se required; however, addressable does not mean optional, and I'm not saying that as I don't think addressable should mean optional. I mean addressable really doesn't mean optional. It actually is a process by which, and I actually brought my little cheat sheet so I could remember exactly what addressable is. The covered entity must implement it actually if it is reasonable and appropriate which means there's a decision process to engage in about whether there's an alternative that would accomplish the same purpose or in fact what the standard that is attempted to be achieved can be done through another mechanism, and you have to document that.

At a minimum what we're recommending here is that as part of the security risk assessment, entities have to consider how they're going to use the technological functions that are in the systems in order to address those provisions that in the security rule today are required to be addressed. Then the last recommendation is now that these functionalities are required to be in the systems, we think down the road that the office of civil rights should consider an upgrade to the security rule so that those ought to be required as the technology becomes more widely deployed.

Again, and I'll pause after this to take a breath and let Rachel chime in to make sure that I'm not missing anything. Really, we're talking about the attestation for this particular set of meaningful use criteria is twofold—one, that the risk analysis was either conducted or reviewed depending on whether you're required to conduct a full one or whether you're eligible to just review one and that the entity has mitigated the risks identified, and it's really all of these pieces in here. You have a written policy on updates and you've implemented any updates that you've gotten per your policy. You've responded to deficiencies identified in the assessment, and you have addressed how the security capabilities in the certified EHR technologies are going to be utilized. Then ideally this attestation, as with any attestation under meaningful use, should be reinforced through whatever audit program the regulatory bodies put into place in order to ensure that the meaningful use criteria are in fact being met. Rachel, did I miss anything?

Rachel Block – New York eHealth Collaborative – Executive Director
No, I think you nailed it.

Deven McGraw – Center for Democracy & Technology – Director
Well, we'll see in a second.

Rachel Block – New York eHealth Collaborative – Executive Director
Judges give you a perfect 10.

Deven McGraw – Center for Democracy & Technology – Director
Now, this next set of recommendations go not to strengthening the existing criteria that are in the NPRM, but instead restoring but with some clarity a requirement that was in our original meaningful use matrix. Just to refresh our memories, we actually had in the matrix that was approved by the policy committee a requirement to comply with the HIPAA Privacy and Security Rule and some sense that if you were under a formal investigation that you shouldn't be eligible for a meaningful use payment. We didn't provide a lot of clarity on this, and in essence, the response from CMS was number one, complying with the rules is baseline. It's not additional, and then I sort of probed on that at our last meeting, and what I got back was, well, give us a better trigger. Give us something that's certain if we're going to withhold people's payments on this basis, something a little more specific, and so that's what we endeavored to do.

We're putting this back on the table because as we're still sort of working on thinking about what additional privacy and security recommendations might be in order for meaningful use in subsequent stages, at a minimum people should comply with the law. That's what exists on privacy and security today. Of course, it's also true that what exists is not just federal law, but also state law. That is not as easy for CMS to police, but it's certainly something that state Medicaid offices could consider if they sought to sort of under the same theory look to their own laws with federal law as a baseline.

I want to go into the specifics of what we're talking about here because we considered this very carefully and wanted to be very fair and not suggest to providers that they could have their money withheld if somebody just merely filed a complaint against them, so I think we set a very high bar here. What we are recommending is that EPs and hospitals are deemed to not meet the meaningful use privacy and security objectives if they have been found liable, which is a civil penalty term, or guilty, which is a criminal penalty term, and fined for a significant civil or criminal violation.

Let me be specific about what I mean when I say significant. First of all, we think this should apply only if a fine has in fact been levied or imposed, and so it's not being imposed at the complaint or investigations stage or when an appeal is pending. We're essentially letting it go through the entire process so that there is in fact a finding of fault and a fine that's been levied.

In the civil penalty context, there are multiple tiers, multiple levels of culpability essentially, and we are limiting this to the most egregious tier of a civil offense which is willful neglect. It's the top two penalty tiers for those of you who are familiar with the way that the stimulus legislation laid this out, and willful neglect is already defined in the HIPAA rule to be conscious, intentional failure or reckless indifference to the obligation to comply with the provision that was up was violated. It's a pretty high standard, and then of course with respect to a criminal investigation, we would want this to apply only for enterprise criminal liability, not for one individual in your institution who screws up very badly and criminally, but instead, that it be the enterprise is at fault which, to the best of my knowledge, actually has not happened in a criminal context in HIPAA. They've all been rogue individuals that have been problematic.

Now, this should apply ideally in the year when the violation occurs, but we recognize that the appeals process can sometimes wind itself out for many years, and payment may in fact have already been made. Our recommendation here is that it should be subject to overpayment recruitment, of course, assuming the status already exists to in fact recoup those payments. If it turns out that in fact the person wasn't meaningfully using because they were guilty of a HIPAA violation (I'm just going to use the guilt term even thought it's not applicable in the civil context. It's easier for people to understand) in the year when they got the money, and so if that's an open question, obviously, we want to talk about that.

The bottom line here is that any eligible professional or a hospital that's been fined for a significant HIPAA violation (and again, at those levels that I suggested, willful neglect on the civil side, enterprise criminal liability on the criminal side), should not be eligible for meaningful use payments. My understanding is that this is quite consistent with government contractor rules generally which is that you are not eligible either for a government contract or to be paid if you're found in violation of another provision.

Those are really the big recommendations here, and this next set is an indication of some other discussions that we had in the workgroup that I think are largely more work to be done in the very near future that the policy and security workgroup will be doing in conjunction with the privacy and security workgroup of standards, and thankfully, we have some overlap in that regard as Dixie Baker's on our workgroup as well. In general, we thought that this certification standards and criteria are a good starter set on the privacy and security front, but there were a number of things that we thought were missing. I'm just going to give you a couple of examples. It's not a laundry list, and in fact, I think one of the first things we have to do is say okay, what is missing that's really essential to be in the system ideally in stage one of meaningful use?

One of the things that was identified is some either standard or functionality to indicate that the provider who's accessing the data has the authority to access that data and in particular, per a consent or authorization requirement where it either already exists in current law or where it's institutional policy. Then also, we do have effective either tomorrow or Friday depending on how you count the new HIPAA requirement that you have to restrict, you can't share data with a payer if the patient has paid out-of-pocket for an episode of care and asks that it not be shared with the payer. It's not clear how easily that's going to be implemented if the systems don't have some functionality for doing that.

I mentioned data segmentation here, but I mentioned it because it's something that's in the stimulus legislation as something that we have to consider, not at all indicating that we've had any sort of in-depth

discussions about this, but we need to. This is just yet another indication of some things that, I'm not trying to be critical of the privacy and security workgroup of standards because I think they did an excellent job with that sort of starter set of capabilities, but we have some pretty critical functionalities that go to privacy and security that are needed to be in these systems. I think we need to get started on that sooner rather than later, and ideally, the policy decisions would be made by this group first and then we'd be able to give some direction to standards. Essentially, I'm telling you that I think that's the direction that our work ought to go in the future, and it would be nice to get some feedback on that from all of you.

As I said, we're not done. We're just beginning our work in this space, and then I think the last thing, we know also we're going to hear a little bit later in our day-to-day about what the NHIN workgroup has been doing. They're also looking at how to implement a trust framework which includes privacy and security protections, and there's a fair degree of overlap between some of the activities that they've identified as meeting future work and what we're beginning to identify as needing future work, and so our intention is to work closely together so that ideally we can be sort of simultaneously processing multiple things at once and get done quicker. Similarly, with respect to the requirements that are going out to the HIE grantees, obviously, we want to be to the extent that we're setting new requirements that are going to apply in different aspects so that we want to make sure that we're being consistent with respect to those grantees as well. With that mouthful I'm going to stop and take questions. Wait, hold on. Rachel, did I miss anything?

Rachel Block – New York eHealth Collaborative – Executive Director
No, I don't think so, Deven. Thanks.

Deven McGraw – Center for Democracy & Technology – Director
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Before I open it up for questions, can I since at the end of the session want to ask for people's global support, how many recommendations are there in this package?

Deven McGraw – Center for Democracy & Technology – Director
Let's see. There are one, two, three meaty ones. Actually, hold on. With respect to strengthening the current criteria which is to not change them in any way, but to provide additional guidance about how that gets done, make sure they're attesting to both the security risk assessment as well as the updates and addressing deficiencies, that's sort of one set of recommendations. The second set of recommendations goes to restoring the compliance with HIPAA privacy and security rules as an objective and then declaring you to be sort of not meaningfully using if you have been penalized for a willful neglect or criminal violation that applies at the institutional or EP level versus individual employee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Would it be fair to say that one set sort of a lot of the earlier slides really enhances the requirement that's already there, and then you're asking for the second requirement to be put in that payments withheld if they're found guilty by all the criteria that you've outlined.

Deven McGraw – Center for Democracy & Technology – Director
Right, payments either withheld or required to be repaid if they've been in fact paid and it's taken some time to wind through the process. I saw Tony.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
With that as a context, let me open it up. Tony, you get first question, comment.

Tony Trenkle – CMS – Director of OESS
Well, just a couple comments, first of all, I think it sounds like what you're trying to do initially, Deven, is to strengthen what's already on the books. As covered entities they're already supposed to abide by the HIPAA security and privacy rules. Secondly, I guess when you talk about the penalties in terms of those

who've been found in violation of it, I'm trying to think of it from an operational perspective how that would work knowing how long some of these cases can drag on. I know you compared it to the federal contracting process … bidders list. Are you looking at something that would just require payments back in the future, or something would actually bar the providers or hospitals from participating in the program?

Deven McGraw – Center for Democracy & Technology – Director
Not the latter. That certainly wasn't the extent, but just with respect to the meaningful use payments.

Rachel Block – New York eHealth Collaborative – Executive Director
The fact that they would not at that point really have qualified for the meaningful use payments.

Tony Trenkle – CMS – Director of OESS
Okay because some of these violations could be systemic and occur over a period of years, so how would you tie that into what you're recommendation is?

Deven McGraw – Center for Democracy & Technology – Director
I think the way we specifically thought of it is in a payment year if it turns out that you in that year had a violation that progressed all the way, first of all, was at that level where it's willful neglect or it's criminal, and number two it progressed all the way to the point where you were fined and the fine was upheld through your appeals process. Again, we tried to think of what was the most fair way to look at getting really with a narrow focus on the most egregious violations and understanding that the taxpayers would likely be outraged if somebody had a HIPAA violation at that level and then was also getting additional money from the federal government for health IT when they were found to be behaving that badly. The way that we had discussed it is in that year where you had your violation even if the process maybe doesn't wind out for another two years where that fine is upheld through all appeals, it's that year when the violation occurred for which you would be considered to be not meaningful using.

Tony Trenkle – CMS – Director of OESS
Right, but what I'm saying is in some cases it is a single violation. Other cases it's more of a systemic violation that occurs over time.

Deven McGraw – Center for Democracy & Technology – Director
Right.

Rachel Block – New York eHealth Collaborative – Executive Director
That would just be dealt with through the existing HIPAA enforcement process. I think all we were trying to do was directly tie this to the receipt of the meaningful use payment.

Tony Trenkle – CMS – Director of OESS
Right, got it.

Deven McGraw – Center for Democracy & Technology – Director
I think what Tony is saying is if you've got somebody who's violating in more than one year—

Tony Trenkle – CMS – Director of OESS
If there's something within the security risk assessment that they should've been doing and they knew about it and they didn't do it over a period of time, such as maybe encrypting data on their laptops for example and it occurred over a period of years, the violation was reported in one year, but it was something that was systemic over a period of time. You might just want to think about is there some more clarity you can give in that regard. I know where you're trying to get to, but it would be helpful if you could give us some more clarity.

Deven McGraw – Center for Democracy & Technology – Director
We will do that because we didn't get that far. I'll circle back with the workgroup, and we'll get you something.

Tony Trenkle – CMS – Director of OESS
Okay.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David, did you have anything?

David Blumenthal – Department of HHS – National Coordinator for Health IT
I have clarifying question. There are a set of things that have to do with the meaningful use criteria and a set of things that have to do with strengthening existing criteria, a lot of which are administrative in nature, so the issuing of guidance. A lot of this has to do with things that you want either ONC or OCR or somebody else to do. In that sense are they directed at the IFR and the meaningful use rules, or are they simply independent recommendations to the federal government?

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think it's a mix of both. Where we're asking for guidance, clearly, we're not asking for providers to generate their own guidance, so those recommendations about what it's going to take to help providers best comply with this are definitely sort of more directed at the federal government in general, but the ones that go to whether you conduct a review or conduct an analysis or review an analysis and what you have to attest to doing and having a written policy, for example, with respect to technology upgrades and attesting to having one go to meaningful use.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We really appreciate the hard work you've put in and the clarity of thinking. If when you get around the transmitting this, if you get around the transmitting it—

Deven McGraw – Center for Democracy & Technology – Director
Yes, we will.

David Blumenthal – Department of HHS – National Coordinator for Health IT
You could separate and—

Deven McGraw – Center for Democracy & Technology – Director
Well, if the policy committee endorses it. We'll ….

David Blumenthal – Department of HHS – National Coordinator for Health IT
That's right …. If you could relate the recommendations more clearly to whether they are about a rule and what part of the rule or whether they are administrative or recommendations about how we implement the rule, that would be helpful to us.

Deven McGraw – Center for Democracy & Technology – Director
Yes, that's fair.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Another avenue for that is strategic planning recommendations that can go because there's a privacy and security theme, so that's another avenue for that. Judy and then Neil.

Judy Faulkner – Epic Systems – Founder
What if the multi-type organizations, so they have hospitals and clinics in multiple places around the country and perhaps one of them has a famous person show up and that one of them that record is violated, what happens with the entire organization?

Deven McGraw – Center for Democracy & Technology – Director
That's a good question. I think it depends on how they apply for meaningful use payments. If it's individual, I assume that the individual facilities want their own payments … apply as one.

Judy Faulkner – Epic Systems – Founder
… apply as one.

Deven McGraw – Center for Democracy & Technology – Director
If they apply as one—

Judy Faulkner – Epic Systems – Founder
Because that may effect how they apply, how we determine this ….

Deven McGraw – Center for Democracy & Technology – Director
I think it's more likely to affect how they apply whether they want to maximize their revenue, what they're entitled to under the federal law, but my own sense is that if you decide that you're going to apply for meaningful use as a group of institutions versus allowing each institution to get its full, if each institution wants its full payment from CMS that they would be entitled to under meaningful use, then that institutions violation, that would trigger what we've talked about here. If they apply as a group but they're still getting individual payments, we're talking about applying the penalty to the institution that had the violation and that is trying to be a meaningful user. My short answer to that question, I had to wind my way through it, is if you applied for meaningful use, the criteria about whether you haven't met it because you have a HIPAA violation that fits these parameters that we've set forth here today, then that's who it applies to. You won't be held responsible for what some other institution did even though you might be part of maybe the same system. If you've applied individually for meaningful use, then you're responsible for your own behavior under the rule. Does that make sense?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
In a health system with 20 hospitals, do they have 20 tax IDs?

Deven McGraw – Center for Democracy & Technology – Director
They have 28 Medicare numbers.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, but it would be essentially back down to the tax ID is how you would apply and then who would be affected.

Tony Trenkle – CMS – Director of OESS
Right, as they apply, then it would tie to that penalty.

M
… some clarity on this, I guess, as someone who works for someone who's famous and people are interested in his medical history, if there's somebody curious that does violate that, is that a criminal offense, or is an institution punished for that offense?

Deven McGraw – Center for Democracy & Technology – Director
It all depends on how the enforcing authorities handle a complaint. If someone has their records breached in an institution whether they're famous or not famous and there's a complaint filed with the authorities about that and they investigate it, in order to reach this level where they'd be ineligible for a meaningful use payment, they would have to be found by an authority and fined by them and have that fine upheld because it was willful neglect or conscious, intentional failure, or a criminal violation that was at the institutional level. In the case of the record-snooping, for the most part to the extent that any criminal fines have been levied, they've been levied against individuals, and we're not suggesting that the institution be penalized for a rogue employee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil and then Art.

Neil Calman – Institute for Family Health – President & Cofounder
I think we have a public relations problem here. That's might be scarier than the idea that providers have to report on 25 different quality measures, and I have a specific recommendation and that is that we not take all of the HIPAA stuff and everything and put it on top of what we're saying about meaningful use so that it doesn't appear like we're creating all of these regulations around meaningful use which I think is one way that you can sort of hear this.

I think institutions, we're all used to dealing with this, but in the provider community, there's not a policy. There's probably not a written policy about almost anything, so all of a sudden that they're going to have a written policy about how they're going to do software upgrades is probably not really something that's going to happen and then to what extent?

If my wife weren't in law school, I wouldn't know what any of these legal terms meant, but to start talking about willful neglect and all these things and putting all of these terms out for providers, I think it's going to terrify people. What are we talking about; what are the rules; and how am I possibly going to know all these things; and how am I going to comply with these things?

I guess my specific recommendation is that we just be very concrete and very clear about how we communicate this because I think it's incredibly important that people do this stuff, but I also think it's incredibly important that people not walk away thinking this technology comes with all kinds of new laws and requirements and potential penalties and there are all these criminal things that could happen to me, and I think you could easily walk away from this and feel like you are now subject to all kinds of things that you weren't before that are pretty scary.

I guess what I'm saying is our communication around this needs be in really simple language, and we need to communicate it simply and make it clear that people are subject, for some of these we're helping people because they're subject to these laws anyway and not make them feel like all of a sudden all this stuff that really is OCR's responsibility and all of a sudden just comes down on them because they're applying technology. I don't know if any of that's clear, but I'm trying.

Deven McGraw – Center for Democracy & Technology – Director
I see what you mean and it's the rub between, I guess attention of piling too much on to meaningful use, and that's why for the most part much of what we said is already existing legal obligation, and we're just making it clear that when you've been with respect to the fines that we're talking about, I just happen to think we'll have a public relations problem on the other side if we let people collect tax dollars who have been found to be egregiously violating HIPAA. Having said that, your messaging points are absolutely right on, and I wouldn't disagree with them at all.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Yes, this is Art Davidson. One of the recommendations you have kind of makes me want to ask Tony a few questions.

Deven McGraw – Center for Democracy & Technology – Director
Sorry, Tony.

Art Davidson – Public Health Informatics at Denver Public Health – Director
This recommendation attestation should be reinforced through audit, and in the NPRM there was extensive effort to document the anticipated burden on nearly half a million eligible providers and 500,000 hospitals around the country. Do we have any idea what the burden would be on Medicare and state Medicaid agencies with regard to these types of audits?

Tony Trenkle – CMS – Director of OESS

I'm not going to give you a specific answer, but in general that depends on the type of auditing we have to do. Obviously, if we do in-person auditing as opposed to auditing through other vehicles, it's going to be much more labor intensive and resource intensive, and part of that is what we're looking at now as we begin to develop an audit program for Medicare and Medicaid. I can't give you a specific answer at this point, but it could be much more of a burden depending on how we implement it.

Art Davidson – Public Health Informatics at Denver Public Health – Director
I didn't expect you to give an answer. I think it's more the point that this is an important area, privacy and security, and we need to be able to prove that what people attest to really happens if we expect people to buy in to the idea that their medical records would be electronic. It just makes me think we need at some point to start figuring out what that cost would be and what is a sample size that would be appropriate for this massive number. Certainly, we can't do it all, and some of the things that Deven has been pointing to here actually require someone going to look at a policy that lives inside of an eligible provider or hospital organization. It's just something for the policy committee maybe to consider.

Tony Trenkle – CMS – Director of OESS
I think some of these go beyond this particular meaningful use discussion. They're really policies that are there already. I think what Neil was saying is there's a perception issue that we have to deal with, and we have to deal with that with the audits as well. We want to make sure we do the due diligence with audits. We need to make sure we do the due diligence with HIPAA privacy and security, but at the same point, we don't want to get the community thinking that adopting EHR is just going to result in greater scrutiny and greater "I got you."

It's a balance, and same with the resources being used to audit. We have to do enough auditing to satisfy that we're meeting the needs that Congress and GAO and other outside auditors are going to be looking at as to say are you doing the due diligence to run the program properly. At the same point, we do have limitations and resources as well. Those are the kinds of things we're looking at within CMS in terms of evaluating that, and the states have to do the same thing working with us.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, Christine.

Christine Bechtel – National Partnership for Women & Families – VP
First of all, terrific job to you and Rachel, Deven.

Deven McGraw – Center for Democracy & Technology – Director
And the workgroup.

Christine Bechtel – National Partnership for Women & Families – VP
And the workgroup, yes, for a good set of recommendations. I have a question about I'm just going to give you slide number. It's slide nine, and it's the piece about you can't take any money on the one hand when you've been found guilty or liable on the other. My question is that's a really high bar it feels like to me. You have to be enterprise-wide, not an individual bonehead (technical term), things like that. Sorry, it's getting late, and you have to actually be guilty, so my question is, is there a bar that's like a notch or two down somewhere between this and you just having an investigation, somebody's filed a complaint, but is there something in between that you guys considered?

Deven McGraw – Center for Democracy & Technology – Director
What we first put on the table was if you've gotten a letter from the Office of Civil Rights saying that they are considering imposing a fine on you for a HIPAA violation which if you think about how the enforcement office has worked historically where they have emphasized more of sort of voluntary compliance that would in fact be a big deal arguably, but a lot of people were very uncomfortable about this guilty until proven innocent nature of that and the sense that the government you know today is not

the government you know tomorrow and that you needed to let the process wind itself out and that people would feel more comfortable if they had that ability to do that before they were faced with having to either pay back or be barred from a meaningful use payment. Some of this is about what you can get consensus on, so I might've pushed that bar a little lower, but I think it's important that it be set where it is. I think it sends a very strong and important message.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It was either that or constitutional amendment. Judy, did you have your hand up?

Judy Faulkner – Epic Systems – Founder
I was just thinking I've spoken to two organizations that had problems of this sort, and both are large. In both situations it was rogue employees. In both situations it was isolated and that organization itself had various precautions and it was still gotten around. In both situations the organizations apprehended the employees and terminated them, and in both situations they were fined at the highest level that they could be fined.

Deven McGraw – Center for Democracy & Technology – Director
No, they weren't.

Judy Faulkner – Epic Systems – Founder
That's what I was told.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

Judy Faulkner – Epic Systems – Founder
Okay, so maybe it was fined to the highest level they could be fined under whatever level it was.

Deven McGraw – Center for Democracy & Technology – Director
Actually, you raise a good point which is something that I didn't bring up which is the issue of monetary settlements. What we've had to date in terms of HIPAA enforcement on the civil side, not the criminal side which have all been, again, against the bonehead rogue employee, but there have been civil monetary penalties that have been assessed against a couple of institutions. Those are monetary settlements.

Now, the institution is paying, and they're under investigation for HIPAA and we didn't have enough time to spend in the workgroup talking about this, but my sense was, and this is my with my lawyer hat on, is that monetary settlements usually are always with a nonadmission of guilt. You don't go through the process. You say, okay, I'm being investigated. I would really like to clear this up and move on with my life, so I'm going to enter into a settlement agreement with the regulators. Yes, I'm going to pay, but there's no finding of guilt, and it doesn't go through an appeal process.

We didn't as a workgroup have time to discuss it, and so if the policy committee wants to do so because you do have somebody paying what is sometimes a significant amount of money for an alleged HIPAA violation, but given where the workgroup was generally which was much more comfortable with if you've been found guilty of something very serious and you're being fined which hasn't happened. There have only been monetary settlements which mean no findings of guilt and no appeals process is triggered. Then people were much more comfortable with that in part because in some respects the institution has sort of had its say and you can bring this in fact to an administrative law judge, an objective person to

weigh the case that the regulators are bringing against you versus your own evidence. I'm getting a cheat sheet. I know who this is from. That's with respect to federal.

Now, can state authority, and we actually did not, now, we do have an ability for HIPAA to be enforced by state attorneys general now, but our specific recommendations were limited to what the federal regulators do because again, if the states wanted to assert and ask for some additional Medicaid criteria along the same lines, that's within their purview to do so, but we were dealing with the federal.

Judy Faulkner – Epic Systems – Founder
Okay, that's probably the explanation right there.

Deven McGraw – Center for Democracy & Technology – Director
Somebody understood your question way better than I did, but it's also good to get out the monetary settlement piece. We did not specifically put that in, in part because we didn't have a lot of time to discuss it and there is no admission of guilt in settlement most of the time. Otherwise, why would you do that?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle.

Gayle Harrell – Florida – Former State Legislator
I want to go back to the public perception problem and public perception among providers versus public, and I think that is a dilemma that has got to be addressed. In the long run without public trust in what we are doing, we will never have adoption of electronic health records, so public perception comes long before provider fear over new compliance issues that we may have to put in place. I think a lot of providers and especially small providers may be concerned about that, but they have that obligation already, and many of them back when HIPAA was first put in place had all kinds of compliance manuals that you had to do, and there was a whole cottage industry of compliance officers who ran around to practices putting place compliance manuals. Nobody's looked them I can tell you since then, and perhaps they need to look at them. Although I speak frequently on behalf of small providers, I think this is something where public perception and the public trust in what we are doing out trumps anything else.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
A couple of points, the recommendations you've made I think do a very nice job of trying to limit the burden on meaningful use to assure privacy and security because as you recognize, there's only a certain amount that can be done through any one policy lever. We've said publicly before and I want to reiterate that the Office of the National Coordinator is not limiting its interest in privacy and security to the meaningful use domain, and we have asked you, Deven, and others to work on this for us, so I just want to emphasize that again.

The other point I have is somewhat a more limited point, and that is, is it possible that by upping the cost of violating the meaningful use criteria and losing all that meaningful use money that you will in effect push everyone to settle and you will never have any opportunity to bring this criteria into effect? The reason I'm saying that is that the maximum annual penalty as I understand it for a HIPAA violation is about $1.5 million. If you're a large institution, the losses associated with losing meaningful use status could be in the tens of millions of dollars and over multiple years many times that. Looking at that

jeopardy it would seem to me that an institutions lawyer would say you can settle for $1.5 million or you can take the risk at $35 or 40. Is this going to have any meaningful effect I guess is the question?

Deven McGraw – Center for Democracy & Technology – Director
I think it's a really good question. Part of the justification for limiting it to the most egregious offenses is I think you're essentially on notice that one of those is pending against you I think you probably have a pretty strong incentive to settle irregardless of whether your meaningful use payments are at stake because it's a huge public relations disaster for you if you pursue this and you're found guilty and you can't overturn it on appeal. Having said that, does this put another thumb on that scale because there's more money at stake? Yes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other comments or questions? I wonder if we could take those two clusters of recommendations. One is really beefing up or enhancing what's there in terms of defining precisely what it means to comply with the results of the security assessment, etc. and then the reinstitution of the withhold. There is some question on that second one I think. Along with David's request in the first one to divide what's recommendation for ONC versus what you'd recommend to put in the meaningful use criteria. For the first category which is beefing up, enhancing the definition and precision with which an organization would be held accountable for meeting the privacy and security HIPAA standard, is there agreement with those sets of recommendations, supporting that? All in favor? Any opposed?

Okay, the second one is reinstituting the penalty or the cost of not meeting the HIPAA rule from a privacy and security point of view. What's the agreement on that? All in favor? And Opposed? Okay to both of them. Thank you and we're almost on time.

Deven McGraw – Center for Democracy & Technology – Director
Yes, I think I ended up using the 15 minutes I gave you back.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's okay. We've made it up other ways. The next workgroup is the NHIN workgroup, and that's represented by David Lansky on the phone. I don't know whether Danny … here and Farzad? Doug is going to be representing everyone. David, are you still on the phone?

David Lansky – Pacific Business Group on Health – President & CEO
Yes, I'm here, and I assume Doug will help out on the ground there.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I'm here, David.

David Lansky – Pacific Business Group on Health – President & CEO
Great.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay.

David Lansky – Pacific Business Group on Health – President & CEO
We have a slide deck. I'm sorry not to be with you in person, but thanks for indulging this method of communication. We've had a very hardworking group and with very good support from the staff as well. The slide deck here will take you through a repeat of a little bit of what we described to you in January, and then what I want to do is give you a process update on the six phases of work we have in mind for

the next nine months and then a little bit of a deeper dive into the immediate work we've been doing on the role of the enabling organizations to help providers obtain meaningful use by satisfying the HIE requirements.

Let me just jump into the slides …. These should be familiar. We have been careful to articulate our definition of the nationwide health information network to represent a set of policies, standards, and services that use the Internet for secure and meaningful exchange of health information. Our charge as a workgroup is to develop recommendations for both the policy and technology framework for using the NHIN in a way that's open to all … innovation.

Please do interrupt me if I go too fast or address something that isn't clear. The context for our workgroup is certainly the meaningful use criteria and the proposed CMS rule, and we're focusing on the information exchange component of the meaningful use criteria. We're looking at the stage one criteria primarily, and I guess I would just say actually that we are trying very hard to take a very narrow slice of the problem and look really at stage one, just at meaningful use, and just at information exchange requirements. At same time as the last point notes, we want to be cognizant of the fact this is going to evolve very rapidly, so we want to enable users with existing exchange capabilities and technologies be successful next year, but we want to keep in mind that there'll be a long road ahead.

The next slide summarizes the six phases that we are conceptualizing our work in. Phase one is done kind of, and we last month reported to you on some of the key elements that we think have to be addressed to enable exchange. I'll repeat those in a second. Today we'll talk in a little more detail about phase two, and we'll ask for your support of some recommendations regarding the role of enabling organizations and the related services that they offer.

Coming up next month, preview, stage three, we'll address identity-proofing and authentication requirements. Phase four in April, we'll talk to you about directories. Phase five in June, we'll get into a more comprehensive view of the trust fabric. Then looking after the summer, we will address the governance requirements for the nationwide health information network. That's our plan.

The next slide introduces a new graphic. We try to do a new graphic every month. This one is our continuing effort to grasp the different levels of complexity that users might require or take advantage of to support information exchange. I'll say this is a new graphic, and we're still wrestling with it, so you let us know if it's not helpful. These are not meant to be sequential over time.

These are meant to be different levels of complexity to solve a problem of information exchange recognizing that there are some users who will be using less complex technology and will be in less complex environments and frankly less well-supported environments. For example, they may be not part of a large IDN or delivery system with a lot of IT capability to support their information exchange needs.

We understand at the left side of this drawing we will need a less complex mechanism supporting information exchange for those users who are in a less-rich environment and going over to the far right of this diagram where we have been with some of the early nationwide health information network demonstration projects and collaboratives among very robust, richly supported organizations, like the VA or Kaiser Permanente or Intermountain where there's a great deal of capability. Then in the middle which may be where a lot of the first generation stage one users are where they will need some level of enabling technology and organizational support in order to be successful.

Our notion here with the workgroup is to focus mostly on the left side of this diagram and will be somewhere between the first and second boxes in the level of complexity that we're addressing, but we

want to be able to make sure that all those levels of complexity are supported ultimately and that they can talk to each other if you will. What we're doing now as it says on the bullet points here is work is underway to establish the minimum requirements for the local applications, for example, local providers using e-Prescribing services, but do that within a context of a trust fabric which we think applies to the entire spectrum of user complexity.

We have some assumptions we're taking into this discussion. We would like the proposals we make to not interfere with existing information exchange capabilities that are already in place and that reflect existing trust relationships and business relationships. We understand that over time information exchange will both include the existing and new exchange mechanisms. We will expand the scope of interoperability, and we will continue to strengthen the ability to support privacy and security requirements.

The sub-bullet here is merging is an important factor for us as probably for all of us. As just last week the state HIE grants are being put out by ONC, we realize the states are developing their own solutions to some of these problems with the support of ONC. We want to make sure that what we speak to at a national level is consistent with and supportive of what the states are doing, takes advantage of what they're doing, but also gives them some nationwide resources that they can take advantage of. The same is true, of course, for enterprise-level information exchange. The work we do now, we do not want that to create a limit, a cul-de-sac on the ability to get to 2013 and 2015, and we want the elements of the trust fabric to stand the expected requirements for 2013 and 2015.

The next one is really a repeat of what we talked about with you in January, and I'll just skip to the next slide. We realize there are several elements that have to be in place to support information exchange—secure Internet transport, addressing mechanisms including directories to allow people to locate other users, mechanisms for authentication and identity-proofing and validation, and then this larger trust fabric that we'll talk more about as we go through this.

We made some recommendations to you which you supported in January which were that we will need to address meaningful use as our primary framework. We will focus primarily on secure transport of information rather than the content of the information packets. We will need to address directories. We will need to address authentication and identity-proofing, and we'll need to address the trust fabric, so you supported that general direction for us last month, and now we're diving into enabling organizations which is the next slide.

Now, … for the title here is that we want to work on enabling organizations, and we chose that word instead of the word intermediaries because we don't want to suggest that these organizations are somehow gatekeepers or roadblocks or checkpoints to the traffic across the Internet in support of health information exchange. They are enablers of individual users, eligible professionals, and institutions succeeding with information exchanges they want to undertake and that they will do their work within a trust fabric that hopefully we'll make some recommendations about as we go forward and this committee hopefully will support.

The next slide gets into some of the findings we've had as a workgroup, and I'll preview that I'm going to sketch some findings of the workgroup and then each of them is matched to a set of recommendations that we'll present to you today. The first set of findings under standards and services, we note that a set of services and specifications should be determined which will enable a provider to transport information over the Internet in a secure and trustworthy way. We are focusing on well-established standards that already exist for secure transport. We will develop technical and policy recommendations that support interoperability between both the more simple forms of data exchange I mentioned earlier and the more

complex information exchange models, and we are beginning to work on the types of technology requirements as well as policy requirements that will be needed to support these standards and services.

The next slide speaks to the policies for confidence assurance. We recognize the need for a trust framework which will ensure that enabling organizations handle data reliably, properly assure identity, and act appropriately with respect to data they handle. This workgroup will address the mechanisms needed for transparency, oversight, accountability, …, and enforcement with regards to these enabling organizations.

We are not yet certain whether or not we as a workgroup will need to speak to the end user level of confidence assurance or …. We understand there'll be enabling organizations which will help users succeed with their information exchange by dealing with issues like data reliability, identity assurance and so on. Whether or not we need prescribe the way those intermediate organizations work with end users and what requirements they impose on end users is something we have not yet determined. For now we are speaking only at the level of enabling organizations.

The next slide talks about the role of government. We believe government will play an integral role in privacy and security and assuring trust of network. We also believe it plays a key role in identifying the standards and services needed to achieve meaningful use of stage one in assuring that the right services are available if they're not available now to the eligible professionals and in increasingly supporting the interoperability requirements. As a philosophy we will aim for the least governmental intervention necessary to accomplish these data exchange purposes, and I've just distinguished that from the trust and privacy category where we want government to take whatever role is necessary to assure the information exchange is private and secure and achieves the trust of public.

The next set of slides brings us into the recommendations that the group is bringing to you today. We are essentially as you see from this short list going to talk about the policies needed for less complex data exchange and the … capabilities that are required for data exchange. Then we'll talk a bit about what's the role of the enabling organization and what's the role of government. It's possible that government …. Perhaps the government needs to certify or identify which enabling organizations are competent to perform and satisfy the policies and technical requirements, and that's something we will come to. We put the little graphic slide here just to remind you that we are not here trying to solve all of the problems of most robust and rich level on the far right of that picture, but we're really focusing on the left side ….

The four recommendations we bring you today, first, recommendation number one speaks to the policy framework, the less complex information exchange. We note that there is a need for a core set of policies to support these less complex exchanges relating to the provider's identity and the addressing of that provider, the ability to authenticate the provider and assure that the right person is at the other end of the wire, to secure the information sharing and to secure the information routing. Secondly, we recommend that there will be policy coordination between what the state health information exchange programs are undertaking and what the nationwide health information network is undertaking, and we also note that we will develop these policies in coordination with both the privacy and security and the HIE workgroups as was noted earlier.

I would say before going forward that we do have a level of granularity below this level where we are beginning to sketch out what the specific policies will need to be, but we are not yet ready to bring that to you. We really want to see if you endorse the path we're on to develop these sets of policies as they support the enabling organizations, and then we'll come back to you with a little more granularity down the road.

Second slide of recommendations slides is on technical capabilities which pretty much is … that there needs to be a core set of services and specifications that can be implemented by the enabling organization to support stage one meaningful use and then cover the same domains saw earlier—provider addressing, provider authentication and identity assurance, information sharing, information routing, and then here we add directory services which is a little bit down the road in our work plan, but we recognize that is an important function as well. Again, these should be coordinated with state level efforts, and here we add the notion I think or sense that to do this right it has to be validated in the real world, and we would like to take the early steps at defining these specifications and standards, but then work with ONC to support some pilots and demonstrations to validate whether the proposed standards and services are sound and effective in completing our goals. I think ONC does wish to go down that road.

The next slide, number three, speaks to the role of the enabling organization. The first point is we note that these organizations may be of many types. We're not describing the organizational form or role, more that any organization may satisfy the requirements we're discussing. They could be health systems. They could be delivery networks. They could be vendors, existing HIEs or HIOs such as the HSB concept we floated last month.

In addition, as the next point says, some of these services might be delivered through mechanisms other than organizations as we know them. It could be software or other service providers, so we are not prescribing the form of all organizations to support information exchange, but instead we're describing the policies and technical requirements. We expect that for the most part it'll be probably familiar organizations that satisfy those requirements for the first phase of meaningful use. We then note that we will need to explore whether or not these organizations must be certified and in turn whether it's the government that must the certifier. Again, we're not yet ready to speak to that, but we are aware that the workgroup will need to address that question.

The next slide, recommendation four on the role of government, we believe that one of the government's roles is to establish and maintain a trust framework which includes ensuring accurate privacy and security protection to enable information exchange. We note that the government may need to create both structures and incentives to enable integration exchange where the necessary trust between partners or the standards and services do not exist. … as suggested earlier is limit the intervention to those areas where existing trust and existing structures don't exist and take a minimal approach to the government interventional role, next that the government may need to create incentives to promote interoperability of privacy and security which of course are implicit in the entire meaningful use incentive program, and as I mentioned a minute ago that government may need to support real-world testing and validation of the proposed services and specifications so that it can be scalable on a nationwide basis.

So that's the set of recommendations. Just to restate the schedule of upcoming events, we think we can begin to bring back to you next month more details, proposals regarding identity-proofing and authentication and further on directories and then the full trust fabric and then finally the governance proposal, but that's the overview. Certainly welcome comments from Doug or other committee members to clarify anything I said from afar, and then we can do general Q&A. Doug, is there anything you want to add to that?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
No, that's a nice summary.

David Lansky – Pacific Business Group on Health – President & CEO
Paul, why don't we take questions? Maybe Doug can facilitate since he can see people better than I can.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, I'll throw one out there. You mentioned the fact that the enabling organization could include vendors, IDNs, HIE organizations. I'm trying to remember on the Recovery Act, I think the HIE business associate requirements was extended to the HIE organization. Was that correct? And Deven is saying yes, so therefore, a vendor who chose, just to pick an example, a vendor who chose to be an enabling organization could end up having to be a business associate under those circumstances.

Deven McGraw – Center for Democracy & Technology – Director
… the term HIE is not defined. It's just made, the business associate provisions are made expressly applicable to them, so in some respect I think that is probably a regulatory matter that's going to have to get addressed.

David Lansky – Pacific Business Group on Health – President & CEO
Maybe I can clarify, Paul, at least my understanding. What we envisioned at this stage for the minimum services that an enabling organization might offer could be as simple as authentication certificates for some other fairly technical, that is, they may not actually traffic in the data as a health information exchange might normally do. They might only be acting on the security and identity management side of it. In other words, it remains to be seen what functions they would have like Deven's point that may or may not qualify them as HIE for purposes of ….

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
To the extent that they're directory services is breached, of course, that could have some wide-ranging implications. Other questions, comments?

David Blumenthal – Department of HHS – National Coordinator for Health IT
David, this is David Blumenthal. Thank you for this terrific work. It's wonderful to watch this conceptual framework deepen with each presentation. I guess one question I have is whether you think that you have to take this process through to its final September/October conclusion before you will have a full suite of recommendations or before you will be able to help us with guidance for the states in particular and others that want to communicate using the NHIN. I say that because I don't have to tell you of the pressure that organizations and providers are under in the field to begin exchanging information. State are hungry for guidance on how they should use the funds that are now becoming available to them for planning to expedite health information exchange as well.

David Lansky – Pacific Business Group on Health – President & CEO
I think we're very sensitive to the time pressure, and I believe we can be sending out the initial sets of both standards and policy guidance over the next few weeks. I believe it's our hope that there would be enough completeness and clarity on some of those so that whatever pilots make sense could be undertaken this spring, so that is I don't think we will wait to try to present a finished and complete package in September, but instead we will make our best recommendations as rapidly as we can over the next I think month to two months and enable the pilot testing to go forward.

I share your concern because I'm working in the California context, but the states feel the pressure to make their own decision with or without guidance from ONC on some of these specific elements like identity management and authentication and so on, so I think it's very important both that we hear from the states where they're having their process and try to align or take advantage of the work they're doing and at the same time that we provide some uniformity from the ONC platform that can guide all the states as they proceed over the next few months. I think the time pressure is very great because of the rollout on the ground in the communities.

That said, getting it right is important, and we're very sensitive to the linkage between the policy objectives and the technology requirements and the importance of real-world testing. In a domain that's as complex and large as, we don't want to put something out that ends up having unexpected consequences or doesn't perform as we expect it to given the vast scale of what this entails.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, David.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Gayle.

Gayle Harrell – Florida – Former State Legislator
Thank you very much. It's Gayle. My question deals again with the state level issues and how we're moving forward. I know in Florida for instance there was an RSP issue just yesterday or the day before dealing in HIEs and the state entity to put together a state HIE or coordinating … in Florida which of course needs to integrate into this, so I have a great deal of concern about that. Also, do you have any concept of when you're going to come forward with some recommendations specifically on governance because that aspect of it has a tremendous impact on how states do this? Also, on the authentication and the technical specifications where if we in Florida for instance are already putting out an RSP for people to present proposals to the state and you're going down a different track, it presents a real problem in the long run.

David Lansky – Pacific Business Group on Health – President & CEO
Thanks, Gayle, extremely sound questions. We have the same challenges in California. On the authentication and technical requirements front, I think they say within a few weeks we can make available the best thinking of the workgroup and hopefully engage the standards committee as well as the policy committee on seeing if our recommendations are supported more broadly and sharing those as we are in these kinds of meetings with the public and with the states … as actively as possible. Because the NHIN connect work is well understood by most of the parties in the states and ONC has done a very good job of … that work, I do think that for the most part the technical approach that we are looking at will be very well aligned with what I think most of the states are looking at. It'll be as much a question of when and whether this federal program, for example, stands up … authority will be a decision to be made down the road, but I think structurally and architecturally, states will be in nicely aligned place.

The governance question I'm less sure about. My understanding and others can make it clearer than I can, ONC in their cooperative agreements with the states has specified some of the requirements around governance, and there will be there to that degree some uniformity in how HIE governance at the state level is implemented, but to what degree what kind of federal governance model makes sense is something we haven't really begun to discuss. I guess we're very interested in this committee's recommendations on how rapidly we need to address that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let me just address the factual matter about what we have and haven't told the states to the health information exchange cooperative agreement program. We have not told anybody, any state or state-designated entity, how to organize structure or govern the exchange of information inside the states. We have told them that we want the state to bring everyone to the table, so we've specified a collaborative process of organizing at the state level, but that need not be a health information exchange organization.

The theory is that states need to be part of the planning process, need to be leading in some cases or at least major contributors. They need to be at the table, and they need to be playing a forceful role, but it is quite possible that many different models of governance of what you are calling I think nicely enabling organizations may arise within the state, and the states will then have to determine what those organizations are capable of, what they're not capable of, and where the state needs to add or subtract. In other words, we're asking the states to lead, not to perform the function of health information exchange.

There is definitely a timing issue, but there are also quite a number of states that are in the process of conducting health information exchange, so it's not a wilderness out there. There are examples of how to do this, and there are going to be other precedents coming out of this work and out of the NHIN, out of

Doug's work, so we're racing against time to make it available, especially to states that feel the need for federal guidance.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Let me just address the question about the technical specifications and how states could get engaged there. I think it's important to recognize as David just pointed out is that as we explore broadening the NHIN to support a broader range of people and enabling organizations, a critical charge there is to make sure that anything that we do is compatible with the existing NHIN cooperatives and the existing specifications that are out there with regard to the nationwide health information network. There's an opportunity for people to engage now using the existing specifications as well as to engage in this in the process of creating some of these new specifications for this less complex exchange and providing some impact and leadership from the states in that role.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Jim.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Thanks, Paul. This is Jim Borland. I might also point out that there are models for governance that exist. The NHIN has been in existence in various demonstration and pilot projects now for well over a year. The governance process for the current participants is well established, their operating procedures. It's heavy weight, and it is in fact towards the more robust side of the graphic. I think what we need to do is to come up with a way as Doug put it to broaden the accessibility of the current standards and specifications, but I think that we can look to the past and certainly to the last six years of experience that we've gained with issues like trust fabrics and governance and things like that, certainly, for lessons learned and also I think for a more accessible path forward.

David Lansky – Pacific Business Group on Health – President & CEO
Thanks, Jim.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Marc.

Marc Probst – Intermountain Healthcare – CIO
Yes, this probably is on the level of a dumb question, but is there any federal guidance relative to consent, like the opt in and opt out? Right now that is the biggest issue we deal with at a state level, and at least our state's not taking any leadership in that at the moment. Should we look for anything from a federal perspective, or is that left to us in the wilderness?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Do you want to answer that, Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
Sure. We're working with the privacy and security workgroup to develop a work plan. The first thing on the agenda after responding to the regulations that came out is to actually make some recommendations on that very topic, and we're looking to try to have recommendations, and I'll let Deven correct me if she thinks it's unrealistic, but some this spring in the next months. Then the expectation is that we would look at those recommendations and see how we might be able to implement them in our different programs or use them as appropriately through guidance to states, etc. That's front and center on our agenda.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let me take the opportunity to introduce someone who didn't expect to be introduced, Joy Pritts, who is our new chief privacy officer, started Tuesday, and so we're letting her adjust a little bit. That's why I haven't put her on the spot today.

Joy Pritts – Georgetown University – Senior Scholar, O'Neill Institute

… endorse what Jodi said. The first step is to, it's incumbent upon Rachel and I working with ONC staff to put together a specific plan for how we're going to tackle what has bee a vexing issue for probably too long and where there are a number of states that have actually resolved it one way or another, and that experience is of course helpful to look at as well as sort of hearing from vendors about what the technical capabilities are and what makes the most sense. We'll have a very specific plan for tackling this, but I think Jodi's right, that our aim is to try to get something specific on the table in the spring.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good. Any other comments or questions on this? I think this is more of a general direction, less so specific recommendations. Is that correct, David?

David Lansky – Pacific Business Group on Health – President & CEO
Yes, I think that's fair.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All right. Thank you very much, David, Doug.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thank you all.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We'll move into the final panel for at least the formal presentations, and this is on the strategic plan workgroup. As you know the policy committee is going to make recommendations to ONC to update their strategic plan. That is due in May, and so our timeline has been we presented to you before the themes, the goals, principles and objective for each theme. You've provided some feedback. You've supported that direction, and so in the past month we're worked on strategies to accompany those themes, and that's what we're going to present to you today.

We still have another chance. We'll put together a written document for your approval in March, and that's what we'll use to go out to the public because there'll be a public hearing in April, and then the final document recommendations which go to ONC in May, so that's the timeline. To recall, the four themes are one, the meaningful use of HIT. Second theme is policy and technical infrastructure, the third being privacy and security, and the fourth a learning health system.

Our first theme was on the meaningful use of health information technology. You looked at the goals and the principles and objectives before. The strategies we're putting before you are the following—the first strategy is to anchor some of this work towards improving health outcomes. Now, neither this committee nor the Office of the National Coordinator sets those health priorities. A lot of other groups participate in doing that for the country, whether it's Healthy People 2020 or the National Priorities Partnership or other groups. Those groups identify some contemporary health issues the country needs to focus upon, but among those are some that the Secretary or HHS or the President may want to focus on for the purposes of this initiative which is to use HIT to improve upon the outcomes and those priorities. Our recommendation is that identify and endorse some of these key priorities, that there be some process identified, health priorities, that are particularly susceptible or amenable to improvement through the affective and meaningful use of HIT and that these guide the selection of future criteria as well as the measures that people are expected to comply with.

The second strategy is one that we've been working on that is to lay out a roadmap or a glide path is another word we've used for it to sort of set a pathway to becoming a fully effective and meaningful user and achieving the health outcome goals that we set out for the program. As a process, and you heard the earlier discussion, some of these may not all come in stage one, but to the extent that we can expose some of the things that will become mandatory and will be placeholders in stages two and three, that gives all of the community, vendors, and the users a chance to react and to plan for those, so that's another strategy.

The third one has to deal with applying the resources effectively. We all know the smaller provider groups, whether those are practices or hospitals, have less access to financial capital as well as the intellectual resources to dedicate to HIT, so the strategy here is to actively support those primary care providers to achieve the meaningful use. Things like the regional extension centers, the HITRC centers are examples of those that meet follow that strategy.

The fourth is to bring together the public and the private sectors. There are a lot of levers that ONC and HHS have at their disposal, but also setting the strategy and setting the roadmap help to align, coordinate, and influence the application of public and private resources to achieving those goals. The federal government of course is the largest provider of healthcare services through the VA and the DOD, so it plays a number of roles from providing services to paying and has a number of ways that it can help align and coordinate all of these priorities.

The fifth is to, as this morning's discussion illustrates, we don't know all the right answers. We can't possibly get it perfect, but one of our commitments is to constantly update and measure, evaluate what's going on in response to some of these policies and to evolve the policies so that they achieve the best possible results to the policies that are set.

The next strategy is to work on workforce. There are already multiple grant programs out there to address this, but that is clearly a key human capital that is needed in order for any of us to be successful.

The sixth strategy is to talk about how can we support consumers. How can we support both their information needs, but also their interaction with their professional healthcare team?

Seventh being to address, we all know that high tech addresses many of the stakeholders that are necessary in this equation, and it's not all through meaningful use. There are a number of programs, it's well laid out in Dr. Blumenthal's *New England Journal* article just within the past month. There are a number of programs that are helping this cause, but there are also some that aren't participating in the meaningful use incentive program per se. A key area is the hospital-based providers which there may be 27 or 30% of those, and still the nonmeaningful use incentive criteria really helped those providers as well, all of the other programs through ONC, and we want to make sure that they are included in the overall planning alignment and use of resources.

Finally, one of the issues that's been brought up is we do have good EHR products. They could be better. They could be more efficient to use, easier to learn, and not impact provider productivity. A lot of this has to do with usability as pointed out by the NRC report in this area as well, and so that is one of the areas where we think ONC could play a role in helping adoption. Now, Jodi will cover theme two and theme three.

Jodi Daniel – ONC – Director Office of Policy & Research

Thank you, Paul. Theme two is about the policy and technical infrastructure, and the goal is to enable management and exchange of electronic health information through the development and support of appropriate policies and technical specifications. We've already presented to you principles and objectives which was modified somewhat in light of input from this group as well as the workgroup, so I'm going to jump right to the strategies.

The first strategy is to adopt standards implementation specifications and certification criteria that incrementally enhance the interoperability functionality, utility, and security of health IT and support its meaningful use. This goes to all of the work we're doing with the standards reg, but really setting that this should be an incremental approach and that there are certain areas that we need to focus on in adopting standards implementation specifications and certification criteria.

The second is to establish and maintain a certification program for purposes of performing testing and certification of EHR technology. Again, this goes to some of the conversations we've already had here with certification program and our NPRM that is in process.

The third strategy is to assess the need for and implement as appropriate policies and programs related to other health IT products and solutions in addition to EHRs. There was a lot of discussion about we have policies and programs for EHRs, but there are other health IT products and solutions that we may want to consider for development of policies, programs, certification processes, etc., and so the group wasn't willing to say that we needed to do that, but thought it was important to say that ONC should assess the need for this and if appropriate adopt policies and programs.

The fourth, and we had a lot of discussion on this, and we realize we have a lot of strategies here and that they were all kind of grouped under this major heading of enabling exchange of electronic health information to support evolving meaningful use criteria and a learning healthcare system, and there are a couple of different sort of substrategies within this. The first was focusing efforts on exchanging electronic health information on meaningful use health outcomes, so tying our work on promoting electronic health information exchange with the meaningful use outcomes.

The second, adopt and promote a core set of policies and meet a publicly assessable standards, protocols, legal agreements, specification, and services that can enable secure health information exchange. The third was leveraging state and federal policies and efforts regarding health information exchange. This goes to our state HIE program as well as working with public health agencies. The fourth recommended strategy was exploring incentives, penalties, and other mechanisms to help increase the business demand for exchange and encourage exchange architectures that are cost-effective and sustainable. We're trying to get at this technical as a policy, leveraging the government approaches as well as any other kind of incentives for a stronger business case.

The fifth strategy was addressing patient safety concerns that may arise from health IT, so not focusing on how health IT can improve safety, but looking at the issues that have come up and the adoption and certification workgroup is going to look at in their hearing about safety concerns related to health IT that have been raised. The sixth is supporting the expanded use of innovative technologies, such as Telehealth and mobile health that support care communication and coordination among consumers and their healthcare professionals. Then the seventh was to collaborate with federal partners to expand broadband access to support health and healthcare. Those were the seven strategies that the workgroup discussed with respect to the policy and technical infrastructure theme.

The third theme was privacy and security, and again, we've already gone through the goals, principles, and objectives for this. Just briefly, the goal is to build public trust and participation in health IT and electronic health information exchange by incorporating privacy and security solutions in every phase of its development, adoption, and use.

Cutting right to the strategies, the first was assess and implement as appropriate federal policies related to key privacy and security issues, and then we had sort of a whole laundry list of different strategies related to this from implementing the HIPAA modifications that are in the high tech legislation, providing transparency of reported breach notifications aligned with our breach notification regulations, and then trying to analyze those reported breaches to identify common issues to inform future privacy and security policies. The third was to assess the extent to which lawful and unlawful uses and exposures of health information can cause harm to individuals. We're talking about, the example that kept coming out was discrimination, so looking at where privacy and security breaches can cause harm to individuals and identify and implement where possible any new policies to help resolve those particular harms and make people feel more comfortable with health information exchange. The fourth was to assess health IT security vulnerabilities and develop initiatives to mitigate those vulnerabilities and then the last one was assess the existing privacy and security protections for non-HIPAA covered entities and address needed protection, so looking at where there might be gaps in existing federal law.

The second strategy in this set was to review existing privacy and security laws to identify the need for potential modifications and policies to align with emerging health IT and health information exchange capabilities. The group was really focused on looking not only at the HIPAA high tech modifications, but reviewing existing laws to make sure that they align with technology as it develops.

The third was to … promote exiting and emerging technologies to enhance privacy and security to see where technical innovation can help us to a better job at promoting privacy and security. The fourth, to coordinate and engage the states on privacy and security in health information exchange policies through our state HIE grants, state alliance, or lots of different levers we have to do this. Fifth was focusing on best practices and guidance for hospitals and healthcare professionals to implement privacy and security policies defined in our nationwide privacy and security framework that was released in December 2008, so a little over a year ago, but looking at how we can sort of give some tools and guidance to those that have to implement privacy and security policies to implement the best practices that they can in their organization and then using the regional extension centers as a way of doing that, but also promoting wider implementation of baseline security practices across the different entities.

Sixth was include privacy and security policies in meaningful use criteria and adopted standards implementation specification and certification criteria, so making sure that privacy and security is based into our standards and certification rules. Seventh, promote an environment of accountability through public education and effective and fair enforcement of legal requirements. Eight was to develop and maintain a national education initiative to broaden the national dialogue of privacy and security issues and to enhance public transparency regarding the uses or protected health information and individual rights with respect to that health information. Okay, and I'll turn it back to Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Our final theme is to create this learning health system. The strategy is really to continuously benefit from what is learned, not only about HIT adoption, but how it is used to accomplish the country's health goals, so that is job one in the learning health system. The second is to reward, showcase, and leverage the industry best practice. This is the share the wealth versus reinvent strategy. The third is to understand how better so there are more research and development activities to overcome the obstacles that impede us being able to learn even in our own patient population, let alone those of the entire communities in the country.

The second and third strategy is again to (that's another way to cheat to get more in), is to, again, the whole federal and private sectors, how can we put together the common platform so we don't have to reinvent the wheel whether it's at the federal level, at the state level, the common policies, standards, protocols, legal agreements, the things that David Lansky talked about in the earlier discussion. How can we leverage those to build an infrastructure by which we can learn from each other and in our own patient population experience?

The fourth is to develop the educational materials. We have this deficit in terms of health literacy amongst all of our patients and consumers. We need to find ways in parallel in a sense to putting together this infrastructure for learning to be able to raise the overall health literacy and healthy behavior aspects of the entire population.

The final one talks about partnering with the professional societies and boards, not to add another component to their certification process, but really to have some of their certification process even be a by-product of them making meaningful use of HIT. This can become a win-win situation where we talked about in the previous strategy raising the level of the health literacy of the overall population. We can add in this strategy to raise the professional learning that occurs through their use of HIT. Let me open that up for discussion, then, questions. David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I keep thanking groups, but I'm just so impressed with the work that's getting done, and this as everyone knows is a legislative requirement for ONC, and we have to come up with a strategic plan or update, I should say a previous strategic plan. Like many of the groups that are working here for the policy committee, you are giving us incredibly important foundations for our required work and our management and policy, so this is already beginning I think to exemplify the complexity of the things that are on our collective plate and the interdependencies between the many different things we're doing.

The last point on the last slide which talks about communication struck me, and I just want to welcome any comments that people on this committee have or suggestions about communication because so much of what we're doing involves convincing the public and providers to cooperate with the wonderful ideas that are included in these slides, and yet, it's easy to lose track of that incredibly important challenge, especially in government which isn't … on its feet all the time and doesn't always articulate things, especially during periods when we're not supposed to talk at all about what we want people to do. We welcome concrete suggestions on that; however, having said all that, I'm going to surrender the microphone and let people actually comment on the material that was presented.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Comments. Jim.

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
I have one comment related to the overall strategic plan outline and one that's responsive to David's question. I'm just curious. I noticed where with meaningful use with those criteria were very focused on measurable results, and I was wondering, this being an outline, there must be kind of a let's say a more fleshy skeleton that has some specific measurable results that may get folded into the strategic plan, so that's an observation.

David, to your point I'd love to hear Neil's take on this, but since I first got involved in this program project, I've always thought, and my background is in communications, this is part of the discussion that a provider has to have with his or her patient. It needs to extend that trusted relationship, and if we try and do it any other way, if we try and do a top-down from the federal government, even, I'm afraid, from the state level or even the HIE or the extension center level, I think we can facilitate it at those levels, but the conversation has to happen between the patient and the doctor.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Neil.

Neil Calman – Institute for Family Health – President & Cofounder
I had a couple comments in relationship to the things that were, this is an amazingly broad piece of work, and so it's a little hard hearing it for the first time to sort of get your hands around it. There are two pieces, very specific comments both on the first theme, and they reflect the fact that in the first theme there is mention and I think it was bullet four of a reduction in disparities, but there's no corresponding strategy for that, so I think we sort of have to go back and map the objectives to a strategy if we're going to say that we should reduce disparities. We really should have some specific strategies that are related to that I think in the strategy section.

The other piece that sort of struck me was that there was no mention in the objectives of the public health part of meaningful use. The other pieces are pretty much called out here in terms of patient engagement. I know we mentioned population health, but again, in the strategies there's not really. It's more than just population health. The public health measures go beyond just sort of what I think of as population health, anyway, but there needs to be strategies I think mapped to that objective as well in terms of number one.

Then I wanted to sort of just ask a question about something I think I brought up in the very first HIT policy committee group which is do we need a theme around potential legislative fixes for things that as we're going through the current bills and stuff like that we think have sort of been missed opportunity. One of them that we've discussed a few times is that there are certain provider groups that are just left out of the incentive program and that we think might be critical to include. We talked about psychiatrists who might not qualify under either Medicare or Medicaid because of their patient panels. We talked about groups of pediatricians and other people that are left out, and I guess a question about the overall strategic plan is where is it that we have an opportunity to identify those? We talked about the hospital-based ambulatory care providers. There are places where in our deliberations we'd come up with these issues, and I think we need a way to kind of park them or start to develop them so that we can think about

ways of perhaps moving forward with some of those or at least proposing some of those legislative corrections.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Christine.

Christine Bechtel – National Partnership for Women & Families – VP
I have two things, one is a question and then the other is a comment. The question is I'm going to slides 11 and 12, theme two policy and technical infrastructure, and I'll say that I worked as part of the group on one and four, and so I may be absolutely hampered by PowerPoint creating what I think is probably and artificial division here, so with that in mind. I'm not as sure that I'm following the difference in strategies. For example, you have number one being adopting standards around different things, but when I think about the policies that actually need to come in most cases first, I see them reflected, but it's buried in a sub-bullet under four, and it's in the context of exchange of information. I'm not sure that I'm completely understanding this section in this regard because you've got an objective number one that is almost verbatim what you're strategy is except the strategy number one doesn't have a policy mention, and you have policy mentioned sort of a couple layers down in a slightly more narrow context. I don't know if my question is clear, but I'm just sort of confused about what's the intent of this particular section? What's the interplay that you envision between policy and standards?

Jodi Daniel – ONC – Director Office of Policy & Research
That's a good question. I think all of four is really focused on policies enabling electronic health information exchange and focusing on how to promote health information exchange. Maybe because we kind of want all these together, it kind of seemed to diminish the focus on policy, but I think that most of the policy components were focused on exchange, and so that's the way the group had decided to sort of put them all together because it seemed repetitive when we were separating them out.

Christine Bechtel – National Partnership for Women & Families – VP
Yes, I think that I'm struggling with the same thing the clearly the group was because I think I would've organized this slightly differently, and that is to say pulling out, I'm not sure what strategy one means, so beyond that, I would've put two and three under there's one strategy here which is enable exchange, and then there are a bunch of tactics for how we do that. Certification should be part of that. That's really kind of a core function of certification. I think having some understanding, what I'm struggling to understand is the context of one, two, and three if it's not exchange. Does that make more sense? I don't know what it would be. Is it like EHR?

Jodi Daniel – ONC – Director Office of Policy & Research
I think the problem is that one, two, and three might go beyond exchange because they also focus on sort of the standards for the product or the capability of the product which may be both for the operations of a particular organization as well as for exchange. For instance, we have standards that relate to CPOE. That's not necessarily criteria related to CPOE. It's not necessarily about exchanging information with another organization, so the standards implementation specs and certification criteria can be both, and then this one's really focused on the exchange piece of it. It might just be an organizing issue, and any suggestions on how we might organize this better I think are welcome.

Christine Bechtel – National Partnership for Women & Families – VP
Okay, and I know we'll have subsequent conversations, and I think one of the ways that I'll look for ways to make some comments will be around putting more of the context in health outcomes and improvement here because this is really like super tech move data, but for what purpose is not particularly clear in the context, so I'll look for that.

My other comment is under the privacy and security section, and it's around the public education component. I want to say that I think ONC should give some thought. I know that there's an …

requirement and talking with consumers about electronic health information and what it means for them is critically important.

That said, I'm worried that a narrow focus on your rights and privacy and security in the context of the time in which we're asking providers to adopt technology, there is a natural logical leap there which says, well, the physicians are doing all of this, so I guess I really should be worried about privacy and security, and that may or may not be true, but I think it is too narrowly construed. When we've talked to individual patients and their families, we've done focus groups and survey research with particularly caregivers, people 40+ and people with complex multiple conditions. When we ask them about health information technology, they told us very candidly that they see that it's a really promising thing because it meets the two most pressing challenges that they face which are communication and coordination in the system. Privacy and security absolutely arises, but in the context of communication and coordination, privacy and security comes up in a different way than when you force the conversation in the abstract, so I'm worried about forcing an abstract conversation with consumers because when you start with privacy and security as opposed to the context in which it arises, you get a completely different reaction, and you're going to have the right hand and the left hand not only not holding hands, but actually boxing if you're asking providers to do one thing which is adopt technology and then you're raising all these alarm bells with consumers by only going for privacy and security with zero context.

Jodi Daniel – ONC – Director Office of Policy & Research
It's a great comment. Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Other comments, questions?

David Lansky – Pacific Business Group on Health – President & CEO
Paul, I have a couple comments.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Yes, hi, David.

David Lansky – Pacific Business Group on Health – President & CEO
It's David, a lot of great material in here, many, many elements that are worth our discussion and support. … David's communications question, I don't yet feel like we have a grasp on the capital S strategy, and I think we need to do some work to tell the story of where this takes the country, what it looks like when we're "done", and we're at the next major milestone, and what does the learning system look like because I think it's a relatively new concept for most observers and not one that's been generally well articulated. How IT creates the fabric of that learning system isn't generally understood. I hope we can do as this outline fleshes out some work on the packaging, the expression of the grand plan so that it filters then through all these different elements that are individually worthwhile.

I have two other comments that are on the same theme. I think I think we should be strong in talking about how HIT improves health outcomes, not only pegging it to a set of priorities and so on, but actually describing the interplay between the information platform and the opportunity for health improvement. That in turn I think should take us to the value proposition. One of my concerns is that when the stimulus dollars run out what is the business case or the value proposition for IT use going forward absent major changes in healthcare payment policy, or do we need to speak to healthcare payment policy as part of the strategy? I don't have an answer to that now, but I think the strategic plan needs to at least comment on the interaction between the IT adoption strategy and the fairly granular detail that's given here and the other drivers of health system change use, technology use that will or won't support. We touch on that

with workforce and so on, but I think it's a big strategic opportunity, and it needs to be talked about in fairly broad strokes, not just ….

The third area on my mind is what's the role of government in the long-term strategy, and it's implied, for example, in theme four the government's role is hinted at, but I think it's worth pulling out or thinking through broadly what we envision or what ONC wishes to suggest is the role not only of ONC, but the role of government broadly, whether its Congress or other executive agencies or state agencies in supporting health system transformation for the use of continuously emerging new technology. In general I'm a little worried that there's a bit of a review mirror in the strategic model because of the nature of error kind of pointed us to the review mirror of a set of assumptions about EHRs and technology which probably aren't likely to be the case in five or ten years. I hope this strategic plan can lay out enough context about drivers that'll be more durable than just the two or three years we're able to see forward right now. Thanks.

Latanya Sweeney – Laboratory for International Data Privacy – Director
This is Latanya. I sort of have an add-on to that. The two things that came to my mind in thinking about the strategic plan and sort of the moving forward, one, is technical harmonization and the other one is economic sustainability. In … technical harmonization, … we've got a lot of things going really quickly because it's a stimulus bill, and we have had to move very quickly. The HIEs are sort of a little in sync at times with the NHIN working group result and so forth and so on. Meaningful uses … people who are deferring. These are a lot of technical issues that sort of are going to need to be harmonized and sort of revisited. I think that ONC needs a space or an opportunity to revisit decisions that are made now that might have maybe better change later, that they were fine for boot-strapping in the start, but not fine for the long run.

The other issue is economic sustainability. This sort of picks up on what David was saying, but it's also something that some of you already know I've been harping on as a big concern of mine, and it's huge. We're creating a new workforce. What's the sustainability of that workforce? Is it really just going to be a blop and then it's over? The ongoing use which David did bring up of the EMRs, but even the economic sustainability of HIEs, the business cases, we haven't really talked about, we haven't really looked at, and I think that that's something I would encourage the strategic planning committee to think about.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you. David, could I drill down a little bit on your three messages? Your first one was sort of the public messaging, how does HIT improve health outcomes. Are you saying that that should be an additional strategy meaning essentially it still goes with David Blumenthal's communication to all stakeholders, or are you saying that the strategies that are currently proposed as draft would not meet the improvement of health outcomes' goal?

David Lansky – Pacific Business Group on Health – President & CEO
I think there's a layer missing, a connective tissue between the grand notions of the learning health system and the individual elements that the committee has begun to package in the outline. That middle layer is some kind of, not exactly a theory of action, but it's an understandable set of relationships between the many elements we've identified and the ability to drive change in practice and in individual behavior and so on. I think articulating that layer, both for our own benefit and then expressing it publicly is an important task.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
To drill down a little bit more on that, is it satisfied by a textual documentation of that connective tissue, or is there a strategy about the connective tissues that's missing?

David Lansky – Pacific Business Group on Health – President & CEO
I think both, but it would need more careful dissection …. I think exactly the point Latanya made and I made, for us to achieve the learning health system is obviously more than a matter of EHRs or meaningful use, and maybe this takes us out of scope, but I think we have to speak to those other forces that will ultimately effect adoption and real use and evolution of the technology in ways that enhance health outcomes.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Any other comments or questions, suggestions? Larry.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare
A short one, there's great, great work here, and I really like the provider neutrality of this, that we're not thinking of individual provider types to say these guys are the leaders or these guys have to figure how to do it on their own, so thank you for that, the implied recognition of all the providers that make it possible to have continuity of care, that if we only support a small group of them that we're sort of limiting our ability to deliver on that vision. I guess I wanted to address the big S strategy piece, really struck me when David said it which is, and maybe it's because it's the end of a long day, but I would like if this really jumps off the page at me and when I get to this statement of why we're doing this that we really give people stuff to rally around, so giving them all of the sort of technical infrastructure, and it all makes a lot of sense, but at the end of the day, how's that going to help me? The things that are all so obvious to us we don't see them I think need to be stated in here.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good advice. If there are no further comments, we'll go onto the public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
This is the public comment portion of the meeting. Anybody in the room care to make a comment? Let's just wait one minute. You, sir.

<Q>: Hi, can you hear me? Good. My name is Zorba Paster. I'm a family practitioner. I teach medical students. I've been in family practice for 30 years, and when I first started I joined Dr. Kellogg in 1949 when we had paper records, and we migrated to the electronic medical record about four years ago. I'm also head of our institutional review board at our hospital, St. Mary's Hospital, …, and I'd like to talk just a little bit about privacy issues and the medical record because we had a few situations, and I just want to talk about them.

I think patients can opt in or opt out of having all of their records sent, and I think that if you imply to a patient that you can expunge some of the information from the record that you are doing them a disservice, and I'll give you a perfect example of something that happened this last week. I had a patient who had a basal cell carcinoma, and a pathology report was on the chart from that. I was out in Colorado visiting my daughter skiing, and the pathology report went to my partner and then sent it off to dermatology. Now, if you look at that pathology report, you would make an assumption it's only pathology which would seem reasonable, but right on the pathology report is a list of all the medications for that patient. One of the medications for that patient was Prozac. Now, if that patient did not want the dermatologist to know that she was on an antidepressant and she said, "Can you only send over my pathology report. I don't want anyone to know I'm on antidepressants," that would be doing a disservice, and I think that's a major aspect with a problem.

With our IRB a number of years ago, probably three years ago, we had a patient who said she was on a study, an arthritis study, and she did not want to have her other physicians know she was in an arthritis study, and low and behold, the records were sent to another doctor. Some of the records, the study records, were not sent because they're kept in a separate folder, but on the electronic medical record in the middle of her previous hospitalization, one of her hospitalizations, it said research drug study, and therefore, that information was then transmitted.

I think that, and I listened to one of the other meetings, to think that a physician or somebody that's able to go through the records and actually remove meaningful information I think does a disservice for the patients, and I think essentially, they either should opt in to have their records transferred or opt out, but to understand that a privacy, some of the information may be transferred, but all of the information may be transferred, and it's really out of their control. They're also out of the doctor's control. I heard at one of the last meetings a couple of months ago that somebody said, well, a doctor can look and take that information out of a chart. In my 20 visit where I have to do health maintenance checks and I have to look at their med list, update their med list and the immunizations, believe me, I don't have the time to be able to go through that record, and I don't have the expertise to go through that record no matter how large it is. Anyway, that's my comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Dr. Paster, and we have nobody on the lines, so I'll turn it back to Dr. Tang and Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We finished. We did everything we set out to do. We finished on time, had terrific work, and I wish those of you who have to travel, safe travels. That means those in Washington because that's where it's really least safe to travel, and we'll see you again in a month. Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you.